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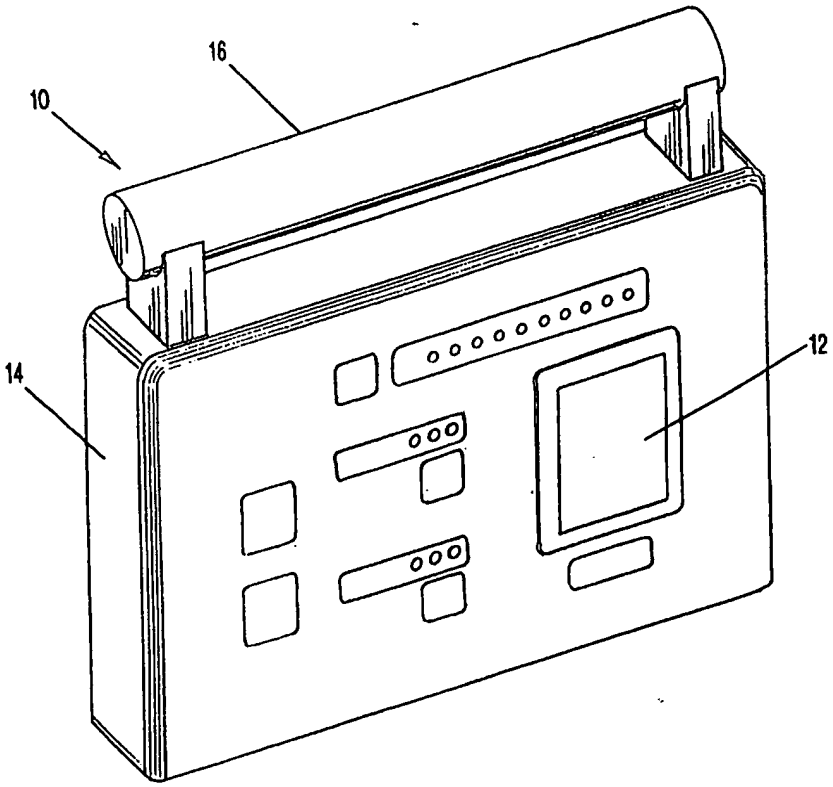
With amended claims and statement.

(54) Title: DEFIBRILLATOR/PACEMAKER

(57) Abstract

A monolithic device (10) for providing defibrillation and pacing of a heart by engaging pacing circuitry once defibrillation has been accomplished. Defibrillation and pacing of a human heart from outside the body employs defibrillation circuitry having an electromotive force of less than or equal to approximately 200 volts. Digital circuitry for generating a direct current waveform to the heart is employed.



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DEFIBRILLATOR/PACEMAKER

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of the filing of U.S. Provisional Patent Application Serial No. 60/052,881, entitled *System for Control of Cardiac Arrhythmia*, filed on July 17, 1997; U.S. Provisional Patent Application Serial No. 60/052,891, entitled *Method to Stop Fibrillating Human or Animal Heart*, filed on July 17, 1997; and U.S. Provisional Patent Application Serial No. 60/079,514, entitled *Electronic Waveform and Generating Devices for Treating Cardiac Arrythmia*, filed on March 26, 1998; and the specifications thereof are incorporated herein by reference.

BACKGROUND OF THE INVENTION

Field of the Invention (Technical Field):

The present invention relates to methods and apparatuses for controlling cardiac muscles, in particular for correcting arrhythmias.

Background Art:

Existing devices for treating cardiac arrhythmia require deployment of high voltages which can, and often do, cause injury to the patient. The present invention permits utilization of low voltages and greatly decrease the risk of further injury to the patient.

An arrhythmia is any abnormal electrical contraction of heart. Particular arrhythmias include: asystole -- no beat at all or "flat-line" on monitor; bradycardia -- slow beat, less than 60 beats per minute; tachycardia -- fast beat, over 100 beats per minute; and fibrillation -- life threatening chaotic heart action in which the heart twitches or quivers rapidly and is unable to pump efficiently.

During fibrillation, less blood is circulating and thus all systems of the human or animal body are at risk. The longer fibrillation continues unchecked the more likely death will occur. For every minute of fibrillation, a 10% reduction of life potential is subtracted, i.e., ten minutes results almost

certain death. During fibrillation the electrical system of the heart is disorganized and erratic. The normal rhythmic beat is totally lost. Serious life threatening events begin to occur. Breathing becomes erratic and then stops as electrical failure begins. Shortly the inadequate circulation of blood causes organs and tissues to be oxygen starved and cell death begins. When brain and heart muscle oxygen starvation reach crisis points they begin to die and hence the entire body begins to die. At some point the heart fibrillations are not reversible and death of the human or animal occurs. It is important to stop fibrillation and to restart or regain the same level of heart contractions to oxygenate the entire body properly.

Fibrillation is currently typically treated by an electronic defibrillator which delivers a shock via two hand-held paddles. This process is familiar to those who view medical television shows and witness a shock so great that the entire body jumps. This shock is about 2,000 to 5,600 volts for external shocks and 310 to 750 volts for internal defibrillators. Repeated use of such large electrical shocks likely may damage the nervous system to such an extent that disabilities shall be present even if the patient lives. The popular conception is that a defibrillator "puts" a heart beat into a stopped heart. Actually, a defibrillator stops the quivering heart, after which, but not always, the heart may resume a slow beat (bradycardia). Paramedics then can use medications to speed up the heart and/or administer an emergency external pacemaker while transporting the victim to a hospital.

In the science of electromyography there is a graphical presentation of fibrillation on a visual monitor of a heart muscle being affected by a monophasic, biphasic or triphasic spike usually of 25 to 100 microvolts in amplitude and each less than 2 milliseconds in duration. These represent uncoordinated contractions of heart muscle (myocardium) fibers. This is a degrading and dangerous state and does require electrical intervention plus oxygen and cardiac medications in an effort to stabilize or regain a normal heart beat. Perhaps 40% of heart attack victims are in fibrillation when a paramedic arrives. Another 40% might be in bradycardia, tachycardia or asystolic status. The other 20% might have plugged heart blood vessels, bleeding, or other conditions that are not related to the electrical function of the heart muscle.

The present invention provides devices and methods whereby substantially lower voltages and currents may be used to successfully treat heart muscle arrhythmias.

SUMMARY OF THE INVENTION (DISCLOSURE OF THE INVENTION)

The present invention is of a monolithic device for providing defibrillation and pacing of a heart comprising: defibrillating circuitry and pacing circuitry which engages once defibrillation has been accomplished. The invention is also of a device for providing defibrillation of a human heart from outside the body comprising defibrillation circuitry having an electromotive force of less than or equal to approximately 200 volts. The invention is further of a device for providing pacing of a human heart from outside the body comprising pacing circuitry having an electromotive force of less than or equal to approximately 200 volts. The invention is additionally of a device for providing defibrillation of a heart comprising digital circuitry for generating a direct current waveform to the heart. The invention is yet further of a device for providing pacing of a heart comprising digital circuitry for generating a direct current waveform to the heart.

The invention is also of a method for providing defibrillation and pacing of a heart comprising: defibrillating the heart; and pacing the heart within approximately 20 msec of cessation of step a). The invention is further of a method for providing defibrillation of a human heart from outside the body comprising defibrillating with an electromotive force of less than or equal to approximately 200 volts. The invention is additionally of a method for providing pacing of a human heart from outside the body comprising pacing with an electromotive force of less than or equal to approximately 200 volts. The invention is still further of a method for providing defibrillation of a heart comprising digitally generating a direct current waveform to the heart. The invention is yet further of a method for providing pacing of a heart comprising digitally generating a direct current waveform to the heart.

A primary object of the present invention is to provide means by which substantially lower voltages and currents can be used to control cardiac arrhythmias.

A primary advantage of the present invention is that it is lightweight yet can operate for durations of three hours or more.

Other objects, advantages and novel features, and further scope of applicability of the present invention will be set forth in part in the detailed description to follow, taken in conjunction with the accompanying drawings, and in part will become apparent to those skilled in the art upon examination of the following, or may be learned by practice of the invention. The objects and advantages of the invention may be realized and attained by means of the instrumentalities and combinations particularly pointed out in the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings, which are incorporated into and form a part of the specification, illustrate several embodiments of the present invention and, together with the description, serve to explain the principles of the invention. The drawings are only for the purpose of illustrating a preferred embodiment of the invention and are not to be construed as limiting the invention. In the drawings:

Fig. 1 is a perspective view of the preferred control unit of the invention;

Fig. 2 is a graph of the counter-fibrillation (C-FIB) waveform of the invention followed by immediate external pacing, with body resistance of 50 ohms, C-FIB energy of 400 joules, pacing rate and pulse width of 60 bpm and 20 msec, and pacing current of 200 mA 5 seconds after C-FIB;

Fig. 3 follows Fig. 2, but with a body resistance of 100 ohms;

Fig. 4 follows Fig. 2, but with a body resistance of 200 ohms;

Fig. 5 follows Fig. 2, but with a C-FIB energy of 144 joules;

Fig. 6 is a schematic of the preferred hardware of the invention;

Fig. 7 is a diagram of the preferred switch settings of the hardware of Fig. 6;

Figs. 8(a)-(c) is an electrical schematic of the preferred waveform generation circuitry of the invention;

Fig. 9 describes the pins shown in Figs. 8(a)-(c);

Figs. 10(a)-(b) is a schematic of the board components corresponding to Fig. 6;

Figs. 11(a)-(b) is a trace diagram of the solder side of the board corresponding to Fig. 6;

Figs. 12(a)-(b) is a trace diagram of the component side of the board corresponding to Fig. 6; and

Figs. 13(a)-(b) is a schematic of the board component slots corresponding to Fig. 6.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

(BEST MODES FOR CARRYING OUT THE INVENTION)

The present invention is of a system to control human and animal hearts to treat arrhythmias. The invention is intended to override an impaired human or animal heart electrical system and to provide a life-sustaining heart beat. In an external embodiment, the invention superimposes and conducts electrical current via stick-on, non-invasive electrode pads to stop damaging or inefficient heart contractions or fibrillation. In addition electrical energy is applied to the heart in a manner that captures its control and serves as the regulatory force to compel the heart to contract in a manner that circulates blood throughout the body. The purpose of the system is to cause all four chamber of the heart to contract forcefully so as to pump blood and immediately relax so as to allow all four cardiac chambers to fill with blood. The capture of the heart is aimed and causing a pumping and refilling of blood at a rate that causes oxygenation of humans or animals tissues and organs in a manner consistent with life. While the device contracts all four chambers of the heart simultaneously, the normal heartbeat contracts the upper (atrial) chambers first and then the lower (ventrical) chambers last.

Referring to Fig. 1, the device **10** of the present invention provides for the electrical control of the heart muscle and preferably presents electronically monitored feedback on a small screen **12** to provide understandable data for medical personnel. The screen allows presentation of the sinus wave shape, heart rate and records and stores this information for medical record usage. Preferably, voice messages prompt the paramedic after the pacing and sensing electrodes have been applied to the patient, including: (1) no detectable beat - check connections; (2) fibrillation or erratic beat; (3) bradycardia; (4) tachycardia; and (5) stable heartbeat. The main use of the external embodiment of the invention is for first-responder treatment of acute cardiac emergencies, being non-invasive in that it does not pierce the skin.

The use of the present invention for the resuscitation of animals ranging in size from small dogs up to large zoo-kept mammalian species is possible with lower or higher power units for correspondingly smaller or larger hearts than humans have. The heart resuscitation animal models indicate that the larger the animal the larger the heart and the more power will be required to control that heart. The human electronic device is appropriate to treat both adults and children. To accomplish this, the device preferably features an operator controlled amplitude range of sufficient expanse to cover anticipated patient size and hydration status.

The invention is preferably sealed to be usable in wet environments and may be cleaned and disinfected with selected chemical disinfectants. The external embodiment is powered by, for example, one or more rechargeable 12-volt lead-acid gel batteries within the main section **14**. In addition, a cylindrical handle **16** located on the left side of the unit houses alkaline D-cells. The D-Cells can be changed while pacing or counter-fibrillation continues via the internal 12-volt battery(ies).

The invention preferably combines counter-fibrillation with assessment and control functions. Counter-fibrillation utilizes relatively low (less than approximately 200 volts) electrical energy which calms or contracts the heart for 1/2 to 5 seconds and then runs a pacing program (preferably five

to 60 seconds, and most preferably 25 seconds) followed by operator selection of subsequent pacing rates and modes. There are two pacing modes, demand or fixed.

In the external embodiment, up to a certain number (preferably four, three or up to six being acceptable) of sensing pads (approximately 1.5 inches diameter) are placed on the chest and/or back or on pulse points found at the wrists or elsewhere on the body to detect rate of heart function. The sensing pads lead to electronics that immediately report cardiac performance or lack of it. That information is flashed on a screen for operator interpretation. Such information includes basal heartbeat rate, if any, and determines if it is chaotic fibrillation, no-beat or too slow or fast. In addition, it is determined if the heart is fibrillating or is asystolic.

Figs. 6-13 illustrate the preferred hardware of the invention, including a programmable logic controller, an external transcutaneous pacemaker, an interface circuit board, and a battery pack. The programmable logic controller preferably includes customizable software, 24 inputs, 32 outputs, two kilobytes of reprogrammable memory, and input/output expansion capabilities. The external transcutaneous pacemaker provides a constant current source up to 300 ohms, discrete amplitude range adjustment from 20-200 mA in 10 steps, discrete rate range adjustment from 40-220 bpm in 10 steps, fixed and demand mode pacing, adjustable pacing duration from 20-100 msec, and complete manual and software control.

The interface circuit card provides a counter-fibrillation voltage of 3-192 volts, programmable logic input definition switches, programmable logic outputs, and DC power utilization. Example inputs and outputs are shown in Figs. 6-7. Input switches may include counter-fibrillation duration of .5-5 sec over 10 steps, pacer current amplitude starting point from 20-200 mA, counter-fibrillation amplitude setting least significant nibble, pacer rate starting point from 40-220 bpm, counter-fibrillation battery level most significant nibble with two upper bits set as "Don't Care" for use as a 2^n multiplier which extends the maximum voltage from 48 to 192 volts, pacer pulse duration of 0-512 msec with 32 msec resolution, choice of routines, and start/stop control. Output switches may include 3-192 volts over 20 outputs, master output control, counter-fibrillation and pacing output

control selector, biphasic control, pacer on/off, rate, current amplitude, demand/fixed pacing mode, and rate counter reset and pulse duration controls.

A number (preferably three) of pacing pads of 8 to 12 square inch electrode area each are placed, such as with two on the chest and one on the back. The impedance of the body is ascertained to select the starting energy levels for both the counter-fibrillation and pacing modes. These pads do multiple duty as they determine impedance and also are used to apply the counter-fibrillation current and/or the appropriate electrical pacing energy.

The system detects the heart status any time during the use of the device provided the sensing and counter-fibrillation/pacing pads are in place on the body of the patient. In some instances the small sensing pads provide information and in other cases counter-fibrillation or pacing must stop momentarily (1 to 5 seconds) for information on heart performance to be ascertained.

The counter-fibrillation system can apply monophasic, biphasic or triphasic direct current via the pacing pads so as to paralyze the heart muscle (myocardia), but a multiphasic counter-fibrillation waveform is preferred such as discussed in U.S. Provisional Patent Application Serial No. 60/079,514. The time required for stopping fibrillation of the heart shall preferably ranges from 1/2 second up to 5 seconds. Once the heart is counter-fibrillated, the sensors detect calmness or chaos characteristics of the heart and pacing is initiated at the same instant (preferably within 20 msec) that the counter-fibrillator releases its hold on the myocardia. Pacing is preferably operator controllable from 50 to 200 beats per minute. Initial pacing is automatically applied as part of the counter-fibrillation module. The first beats are at higher electrical amplitude to insure capture and control of the heart. Sensors inform the operator, along with observation of life signs, if capture is lost. The operator can repeat the pacing program or can raise the amplitude manually to attempt a re-capture and gain electrical control of the heart's biological electrical pacing system.

When pacing is occurring at the rhythm selected by the operator, the operator may elect to engage a demand mode and transport the victim to the hospital. The demand mode "listens" via the sensors and warns the operator by audible alarm and visually on the monitor screen if capture is lost.

The operator may try to re-capture by manual control of pacing rate and amplitude or he can default to the pre-programmed pacing event if capture and control of the heart cannot be attained.

The invention, which is battery operated for up to approximately 3 hours, stabilizes a heart within approximately one minute after applying of the electrodes, provided the operator has arrived within about five minutes of a heart attack. The fully charged batteries shall be operative for a minimum of 3 hours, but this can be extended by changing the alkaline batteries. Batteries can be changed quickly with little or no interruption of pacing once the patient is stable. The cylindrical case contains alkaline batteries which can be changed as in a flashlight. The rechargeable internal lead-acid-gel 12-volt battery(ies) in the main body of the invention supplies electricity while the alkaline batteries are changed. The cylindrical battery case also serves as a carry-handle. The 12-volt main battery(ies) can also be changed quickly if required. The entire system, including both pacing and counter-defibrillation module, preferably weighs less than five pounds. In models without counter-defibrillation, the weight preferably is less than three pounds. Weight does not include electrodes, sensing pads, or the wiring harness.

The present invention is also of a method of gaining emergency electrical control of a fibrillating heart. The usual cardiac medications, oxygen administration and other treatment can be utilized simultaneously or after cardiac counter-fibrillation treatment is applied. The invention can be used alone for stopping fibrillation or it can be part of a system that deals with all heart arrhythmias. Rather than an analog signal, a digital, software driven, signal of constant direct current is employed to bring a fibrillating heart to a stand-still very quickly. This is important because the longer the duration, the lower the voltage amplitude. The longer duration and lower voltage amplitude can result in the same amount of energy being applied as used today with defibrillators, but usually is much lower in energy. However, the invention begins at a lower electrical energy and then steps up as required until the heart fibrillation ceases. The nominal amount of time applied to each counter-fibrillation power level is about 1/2 to 5 seconds.

When the fibrillation has stopped, the counter-fibrillation electrical energy is released by the software which then instantly activates a special brief burst pacing program to establish a heart beat.

The burst pacing program can last up to preferably 25 seconds. The energy for this particular heart pacing starts high and with each contraction of the heart steps the electrical energy downward by about 15%. If "capture" of the heart is lost, then sensors increase the next electrical energy pulse by an amount, preferably by 30%. If capture is not regained, the algorithm program returns electrical pulse to the highest pacing power and runs that program as long as capture is maintained while reducing pulse power by 8 to 10% every two or three pulses until it maintains control of the heartbeat at a fixed rate wherein the information aspect of the unit prompts the paramedic to select a fixed rate pacing and adjust the power as he deems appropriate while transporting the patient to a hospital. Capture is determined by sensors that detect either electrical activity via electrode pads, mechanical activity through blood pressure and blood flow detection, or both. The sensors, which may be standard, off-the-shelf items, are fed back to the logic control circuitry that makes decisions based upon the sensor's output.

The paramedic can further tailor the pacing program treatment aspect by continuing fixed-rate pacing or switch over to demand mode which monitors the heart and only paces if the victims heart beat drops below a selected rate. The paramedic may also select a waveform or waveform variation stored in software of the control system. Thus, if a patient's heart is beating on its own the unit merely stands by to catch any decaying beat rate. Enough beats are inserted during a minute period to equal the amount called for by the paramedic. Rate selection for demand-mode is operable only between 50 and 120 beats per minute. While fixed-rate pacing can be utilized to pace a heart throughout a range of 50 to 200 beats per minute.

The formula for energy utilized for counter-fibrillation is given by $J = \text{Voltage}^2 \times \text{seconds/Resistance}$. If the analog signal is transformed into a constant DC signal of greater duration, then a substantial reduction in voltage can be achieved. For example, assume a patient's body resistance is 50 ohms and in order to reset the heart it'll require 360 joules. With the present day analog signal technique, it would take approximately 650 - 1420 volts. Now assume that the new constant DC signal duration is stretched out to .5 seconds. The voltage required to do the same amount of work is now 190 volts. The total voltage can be less than 200 volts but more than 60 volts for adults. Children in fibrillation can be expected to be treated with 40 to 120 volts. The selection of

voltage will be relative to the hydration of the patient and their relative body size and frailty Obviously, a much safer situation for doctors, nurses, emergency personnel and the patient. Implantable device voltages are approximately four to eight times less than voltages needed with non-invasive stick-on electrode pads of the invention.

The counter-fibrillation signal can be described by a sharp rise in voltage (slope) for approximately 3 to 5 milliseconds, where it will reach the full DC value and then be maintained (held at constant value) for a variable long duration followed by a decay in voltage very similar to the slope of the rise. The method for up slope or down slope may be in small digital steps or angular cascade in many electrical patterns. This electrical signal can also be reversible as to polarity by the operator. The counter-fibrillation force on the heart can be applied from 1/2 second up to 5 seconds. Time and voltage are gradually increased via instructions from the installed program.

The counter-fibrillation system of the invention and its electrical and electronic controls can be combined with or inserted or added into other emergency cardiac systems as a drop in module. Additionally, the system can be designed into more complex cardiac care systems. It can also be utilized as a stand-alone compact system for first responders to cardiac emergencies.

The electrical patterns preferred are shown in Figs. 2-5. These electrical patterns indicate some of the approaches to stop fibrillation in a human or animal heart. Some variations of these patterns may be made but the inventors are certain that those presented herewith shall stop fibrillation in both human and animal hearts at much lower power than traditionally used. This invention shall more surely stop fibrillation and directly cause heart pacing to occur and do this faster than is currently possible with pre hospital cardiac victims.

The present invention may be used to stimulate contractions of other muscles than the heart where desirable.

Although the invention has been described in detail with particular reference to these preferred embodiments, other embodiments can achieve the same results. Variations and

modifications of the present invention will be obvious to those skilled in the art and it is intended to cover in the appended claims all such modifications and equivalents. The entire disclosures of all references, applications, patents, and publications cited above are hereby incorporated by reference.

CLAIMS

What is claimed is:

1. A monolithic device for providing defibrillation and pacing of a heart, said device comprising:

means for defibrillating the heart; and

means for pacing the heart once defibrillation has been accomplished.

2. A device for providing defibrillation of a human heart from outside of a human body containing the heart, said device comprising defibrillation means having an electromotive force of less than or equal to approximately 200 volts.

3. A device for providing pacing of a human heart from outside of a human body containing the heart, said device comprising pacing means having an electromotive force of less than or equal to approximately 200 volts.

4. A device for providing defibrillation of a heart, said device comprising digital means for generating a direct current waveform to the heart.

5. A device for providing pacing of a heart, said device comprising digital means for generating a direct current waveform to the heart.

6. A method for providing defibrillation and pacing of a heart, the method comprising the steps of:

a) defibrillating the heart; and

b) pacing the heart within approximately 20 msec of cessation of step a).

7. A method for providing defibrillation of a human heart from outside of a human body containing the heart, the method comprising defibrillating with an electromotive force of less than or equal to approximately 200 volts.

8. A method for providing pacing of a human heart from outside of a human body containing the heart, the method comprising pacing with an electromotive force of less than or equal to approximately 200 volts.

9. A method for providing defibrillation of a heart, the method comprising digitally generating a direct current waveform to the heart.

10. A method for providing pacing of a heart, the method comprising digitally generating a direct current waveform to the heart.

AMENDED CLAIMS

[received by the International Bureau on 07 December 1998 (07.12.98);
original claims 1,3,6 and 8 amended; remaining claims unchanged (2 pages)]

1. A monolithic device for providing defibrillation and pacing of a heart, said device comprising:

low voltage means for defibrillating the heart; and

means for pacing the heart once defibrillation has been accomplished.

2. A device for providing defibrillation of a human heart from outside of a human body containing the heart, said device comprising defibrillation means having an electromotive force of less than or equal to approximately 200 volts.

3. A device for providing pacing of a human heart from outside of a human body containing the heart, said device comprising pacing means having an adjustable current amplitude range of between approximately 20 milliamps and approximately 200 milliamps.

4. A device for providing defibrillation of a heart, said device comprising digital means for generating a direct current waveform to the heart.

5. A device for providing pacing of a heart, said device comprising digital means for generating a direct current waveform to the heart.

6. A method for providing defibrillation and pacing of a heart, the method comprising the steps of:

a) defibrillating the heart with a low voltage; and

b) pacing the heart within approximately 20 msec of cessation of step a) with an adjustable current.

7. A method for providing defibrillation of a human heart from outside of a human body containing the heart, the method comprising defibrillating with an electromotive force of less than or equal to approximately 200 volts.

8. A method for providing pacing of a human heart from outside of a human body containing the heart, the method comprising pacing with an adjustable current having an amplitude range of between approximately 20 milliamps and approximately 200 milliamps.

9. A method for providing defibrillation of a heart, the method comprising digitally generating a direct current waveform to the heart.

10. A method for providing pacing of a heart, the method comprising digitally generating a direct current waveform to the heart.

STATEMENT UNDER ARTICLE 19

Dear Sir:

In response to the Examiner's comments in the International Search Report mailed on 08 October 1998, Applicants respectfully request amendment of the claims without prejudice as follows:

In the Claims:

1. (Amended) A monolithic device for providing defibrillation and pacing of a heart, said device comprising:

low voltage means for defibrillating the heart; and

means for pacing the heart once defibrillation has been accomplished.

2. A device for providing defibrillation of a human heart from outside of a human body containing the heart, said device comprising defibrillation means having an electromotive force of less than or equal to approximately 200 volts.

3. (Amended) A device for providing pacing of a human heart from outside of a human body containing the heart, said device comprising pacing means having an [electromotive force of less than or equal to] adjustable current amplitude range of between approximately 20 milliamps and approximately 200 [volts] milliamps.

4. A device for providing defibrillation of a heart, said device comprising digital means for generating a direct current waveform to the heart.

5. A device for providing pacing of a heart, said device comprising digital means for generating a direct current waveform to the heart.

6. (Amended) A method for providing defibrillation and pacing of a heart, the method comprising the steps of:

a) defibrillating the heart with a low voltage; and

b) pacing the heart within approximately 20 msec of cessation of step a) with an adjustable current.

7. A method for providing defibrillation of a human heart from outside of a human body containing the heart, the method comprising defibrillating with an electromotive force of less than or equal to approximately 200 volts.

8. (Amended) A method for providing pacing of a human heart from outside of a human body containing the heart, the method comprising pacing with an [electromotive force of less than or equal to] adjustable current having an amplitude range of between approximately 20 milliamps and approximately 200 [volts] milliamps.

9. A method for providing defibrillation of a heart, the method comprising digitally generating a direct current waveform to the heart.

10. A method for providing pacing of a heart, the method comprising digitally generating a direct current waveform to the heart.

REMARKS

The application entitled "Control of Cardiac Muscle" was submitted with ten claims. The following Article 19 amendments were made to the claims in response to receiving the International Search Report:

Claims 2, 4, 5, 7, 9, and 10 remain unchanged.

Claims 1, 3, 6, and 8 have been replaced by amended claims bearing the same numbers.

The amendments were made in response to the documents considered to be relevant and cited in the International Search Report. Substitute sheets showing consecutively numbered claims 1-10 are attached. Favorable action is requested.

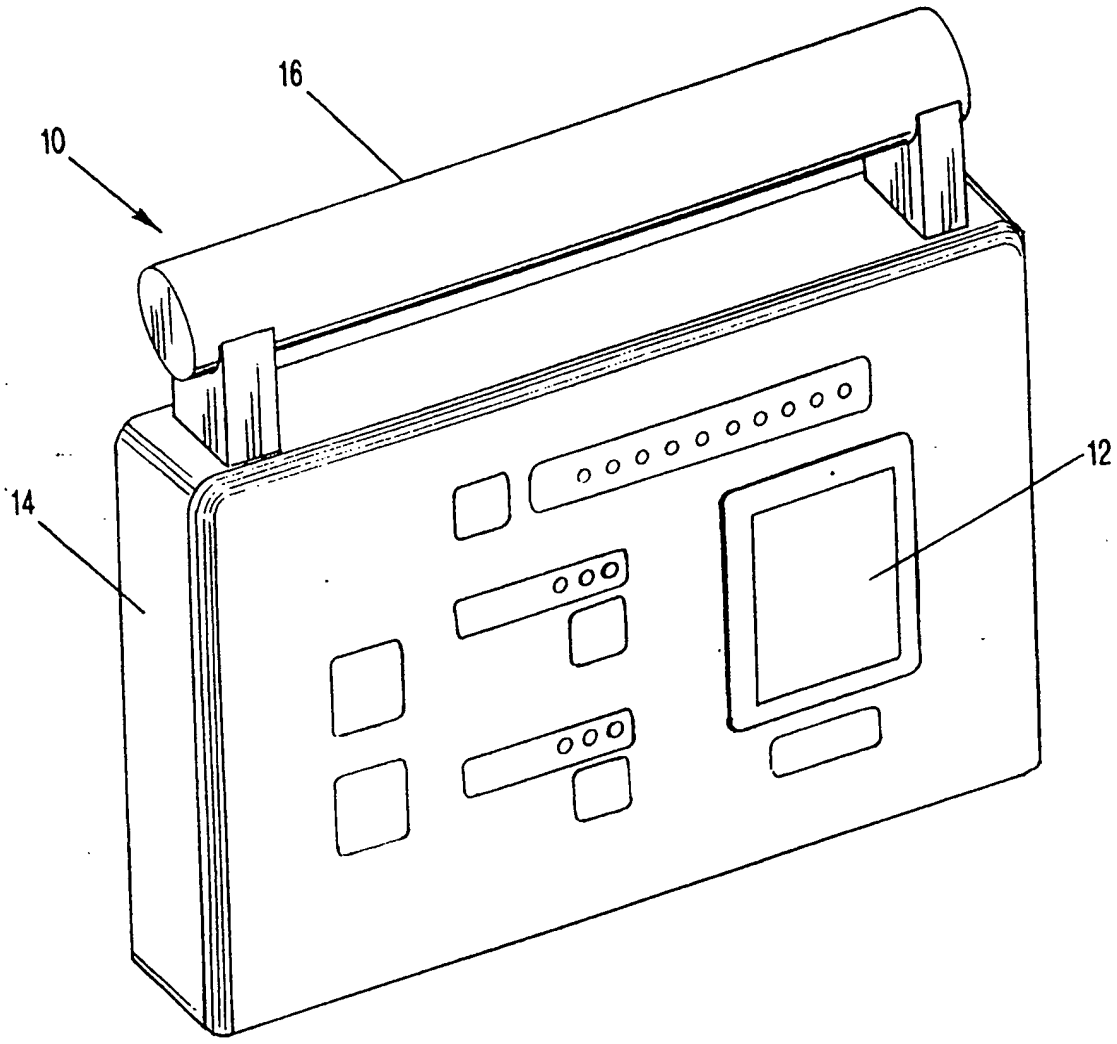


FIG-1

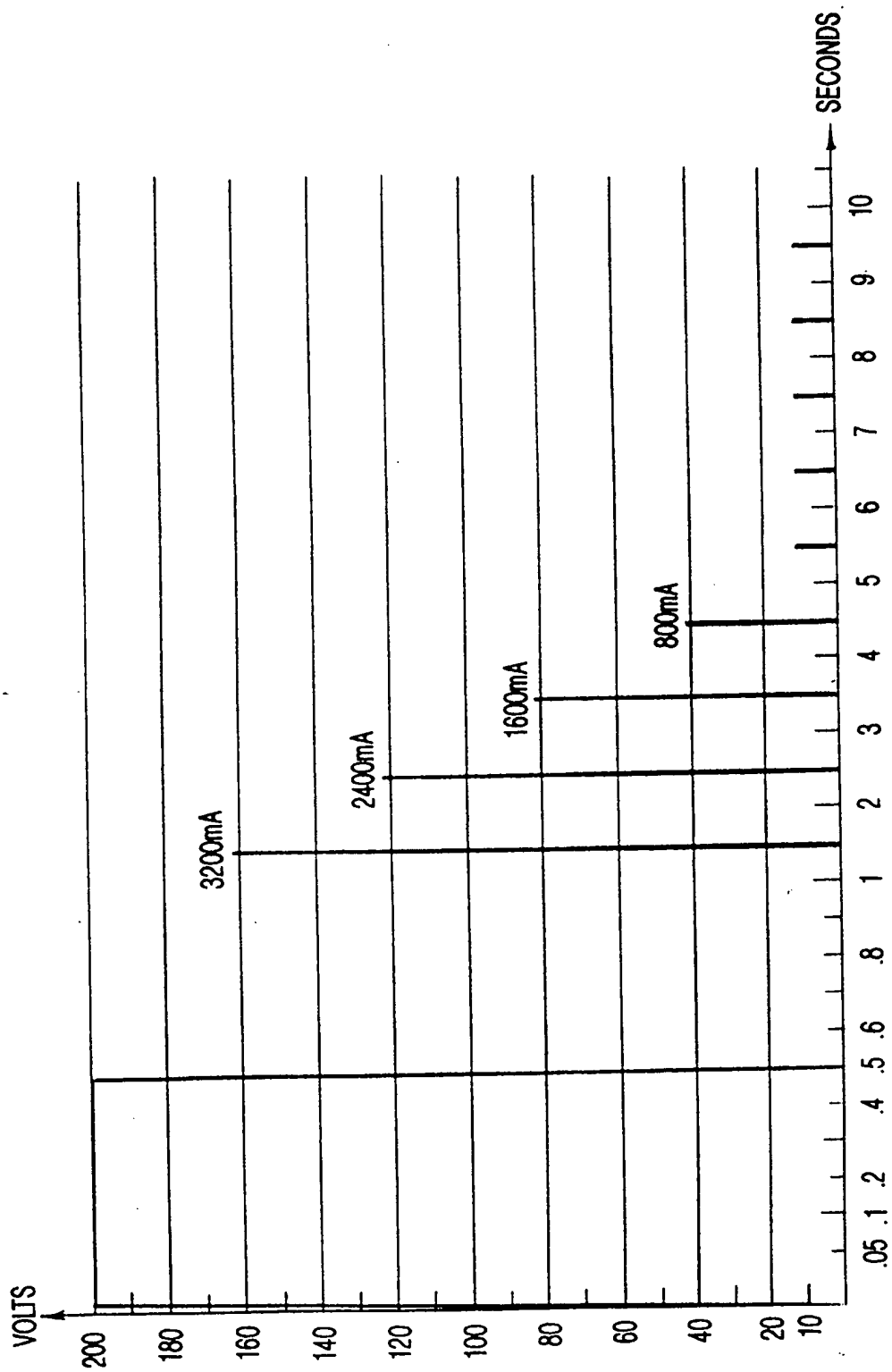

VOLTS
200
180
160
140
120
100
80
60
40
20
10
SECONDS
.05 .1 .2 .4 .5 .6 .8 1 2 3 4 5 6 7 8 9 10
3200mA
2400mA
1600mA
800mA

FIG-2

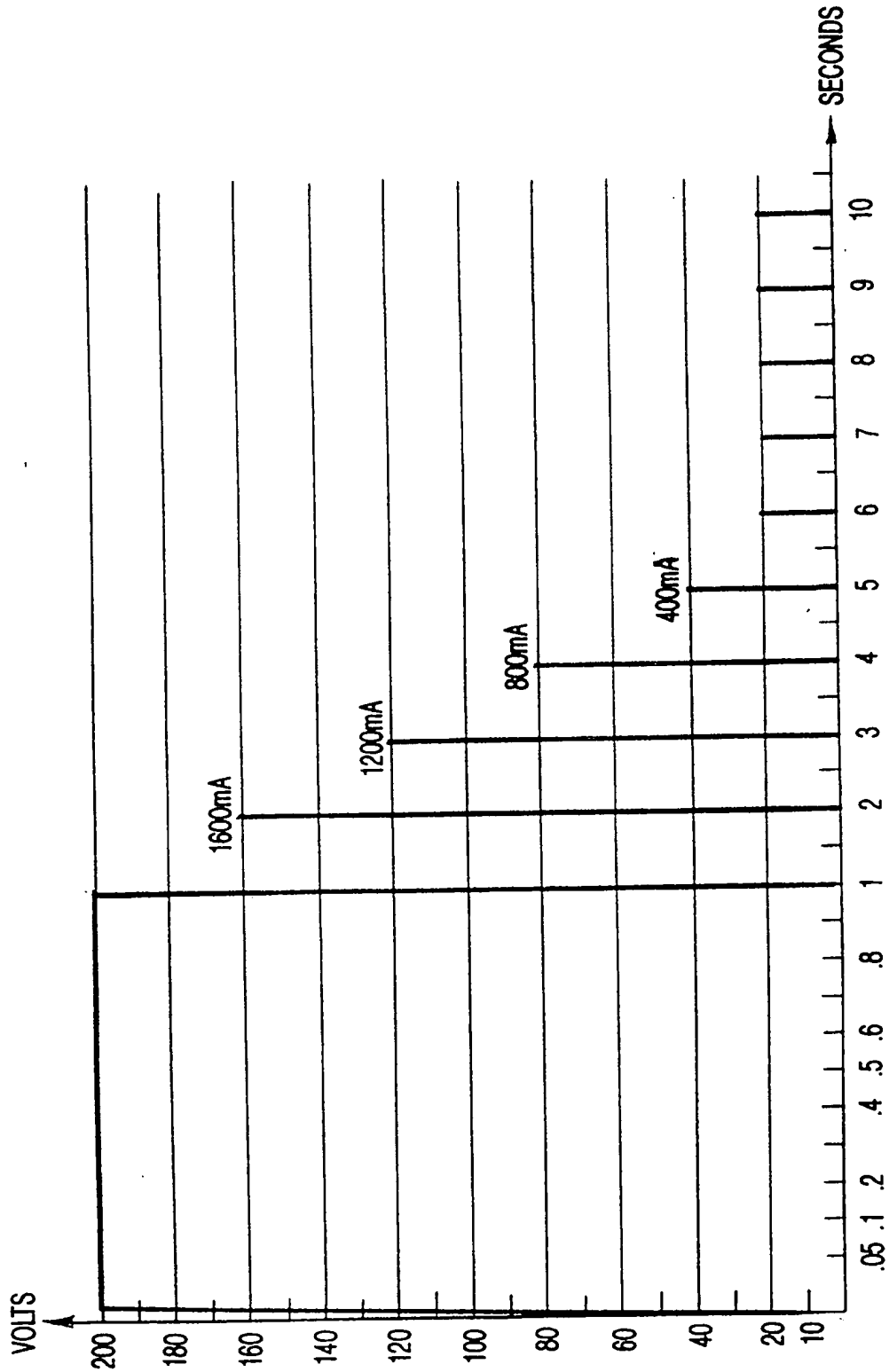

VOLTS
200
180
160
140
120
100
80
60
40
20
10
SECONDS
.05 .1 .2 .4 .5 .6 .8 1 2 3 4 5 6 7 8 9 10
1600mA
1200mA
800mA
400mA

FIG-3

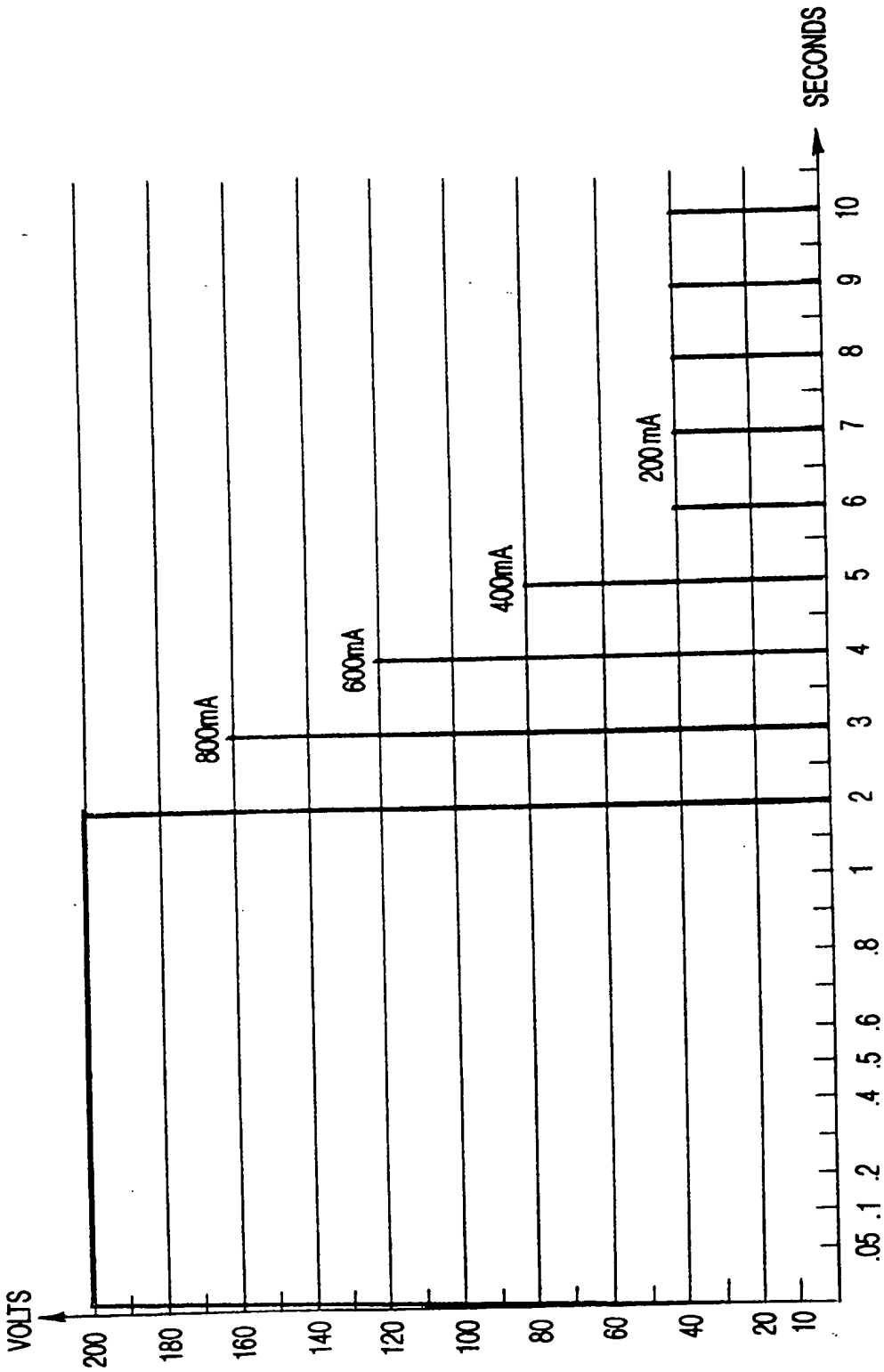

VOLTS
200
180
160
140
120
100
80
60
40
20
10
SECONDS
.05 .1 .2 .4 .5 .6 .8 1 2 3 4 5 6 7 8 9 10
800mA
600mA
400mA
200mA

FIG-4

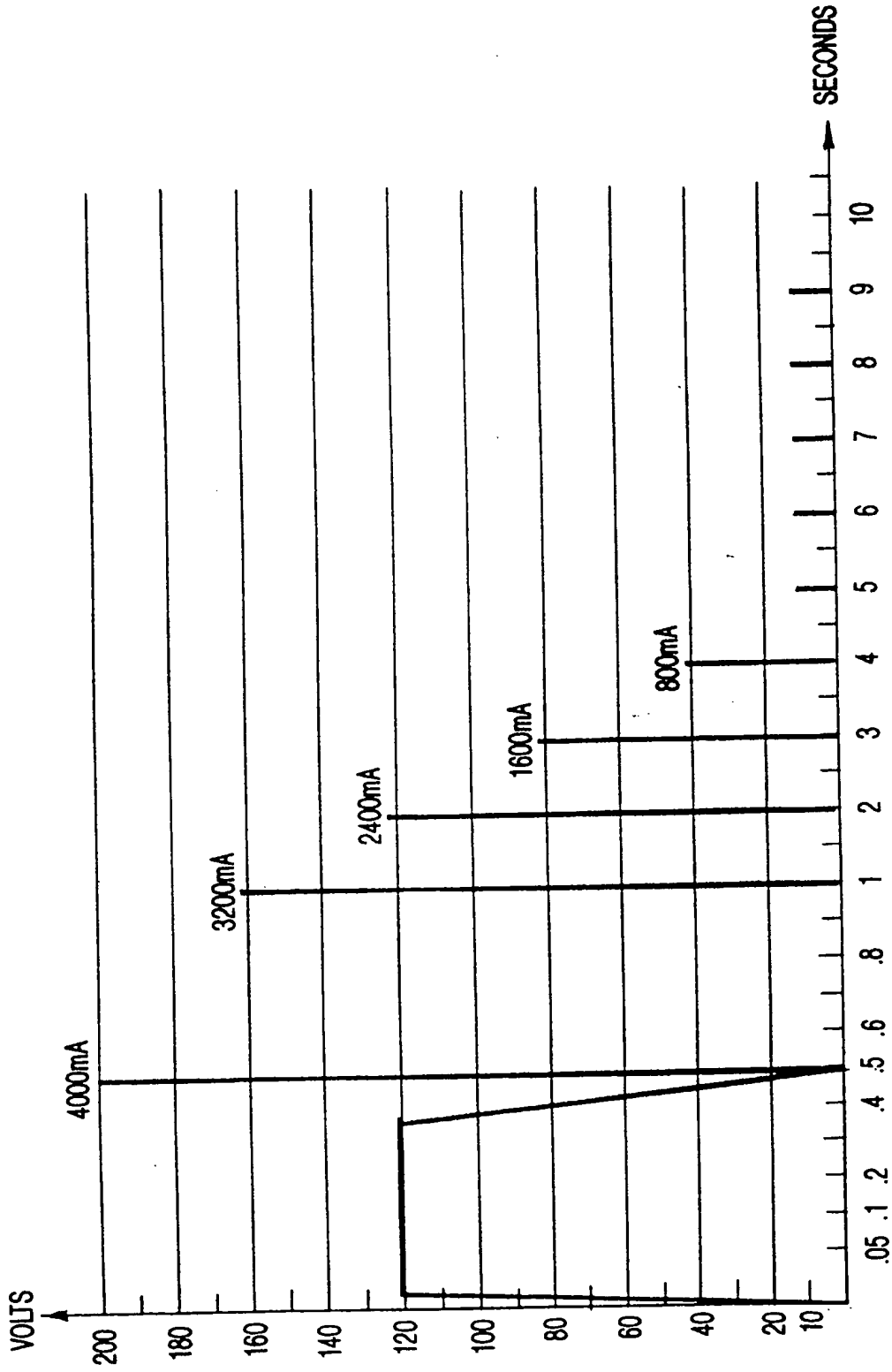

VOLTS
200
180
160
140
120
100
80
60
40
20
10
4000mA
3200mA
2400mA
1600mA
800mA
.05 .1 .2 .4 .5 .6 .8 1 2 3 4 5 6 7 8 9 10
SECONDS

FIG-5

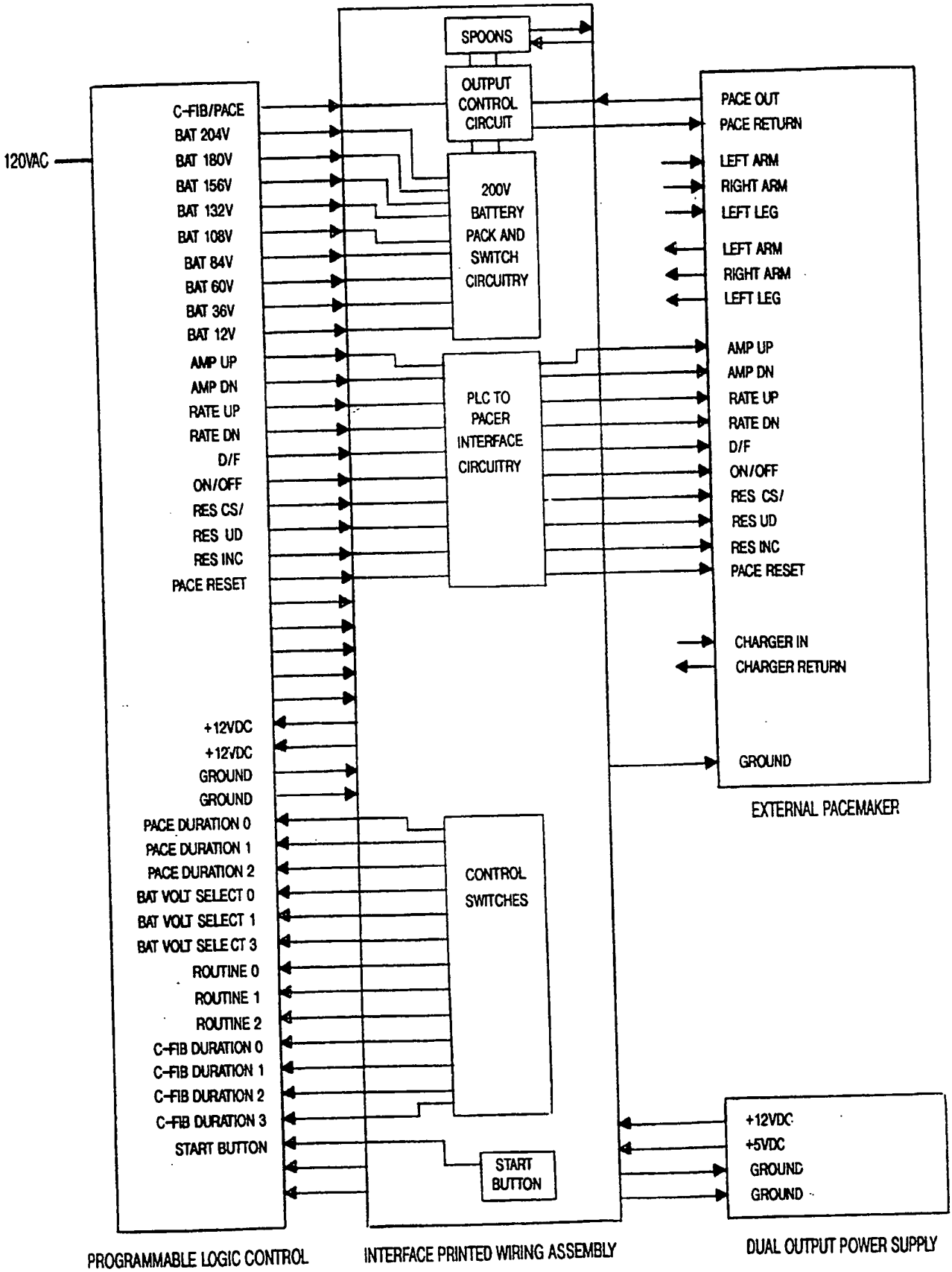

120VAC
C-FIB/PACE
BAT 204V
BAT 180V
BAT 156V
BAT 132V
BAT 108V
BAT 84V
BAT 60V
BAT 36V
BAT 12V
AMP UP
AMP DN
RATE UP
RATE DN
D/F
ON/OFF
RES CS/
RES UD
RES INC
PACE RESET
+12VDC
+12VDC
GROUND
GROUND
PACE DURATION 0
PACE DURATION 1
PACE DURATION 2
BAT VOLT SELECT 0
BAT VOLT SELECT 1
BAT VOLT SELECT 3
ROUTINE 0
ROUTINE 1
ROUTINE 2
C-FIB DURATION 0
C-FIB DURATION 1
C-FIB DURATION 2
C-FIB DURATION 3
START BUTTON
PROGRAMMABLE LOGIC CONTROL
SPOONS
OUTPUT CONTROL CIRCUIT
200V BATTERY PACK AND SWITCH CIRCUITRY
PLC TO PACER INTERFACE CIRCUITRY
CONTROL SWITCHES
START BUTTON
INTERFACE PRINTED WIRING ASSEMBLY
PACE OUT
PACE RETURN
LEFT ARM
RIGHT ARM
LEFT LEG
LEFT ARM
RIGHT ARM
LEFT LEG
AMP UP
AMP DN
RATE UP
RATE DN
D/F
ON/OFF
RES CS/
RES UD
RES INC
PACE RESET
CHARGER IN
CHARGER RETURN
GROUND
EXTERNAL PACEMAKER
+12VDC
+5VDC
GROUND
GROUND
DUAL OUTPUT POWER SUPPLY

FIG-6

C-FIB DURATION SWITCH	
SWITCH SETTINGS	DURATION IN SEC.
0	0.5
1	1
2	1.5
3	2
4	2.5
5	3
6	3.5
7	4
8	4.5
9	5
10	NOT USED
11	NOT USED
12	NOT USED
13	NOT USED
14	NOT USED
15	NOT USED

C-FIB AMPLITUDE SWITCH	HIGH VOLTAGE SWITCH		
SWITCH SETTINGS	(ZERO)	(ONE)	(TWO)
0	4	68	132
1	8	72	136
2	12	76	140
3	16	80	144
4	20	84	148
5	24	88	152
6	28	92	156
7	32	96	160
8	36	100	164
9	40	104	168
10	44	108	172
11	48	112	176
12	52	116	180
13	56	120	184
14	60	124	188
15	64	128	192

PACER DURATION SWITCH		
SWITCH SETTINGS	SELECTION OF K OHMS	PULSE DURATION
0	100	0.1
1	95	0.095
2	90	0.09
3	85	0.085
4	80	0.08
5	75	0.075
6	70	0.07
7	65	0.065
8	60	0.06
9	55	0.055
10	50	0.05
11	45	0.045
12	40	0.04
13	35	0.035
14	30	0.03
15	25	0.025

ROUTINE SWITCH	
SWITCH SETTING	ROUTINE
0	C-FIB PULSE AND 5 TIME CONSTANTS DECREMENT OF PACER AMPLITUDE
1	C-FIB PULSE AND STEADY STATE PACER AMPLITUDE
2	BIPHASIC C-FIB PULSE AND 5 TIME CONSTANTS DECREMENT OF PACER AMPLITUDE
3	BIPHASIC C-FIB PULSE AND STEADY STATE PACER AMPLITUDE
4	STEADY STATE PACING WITH NO C-FIB PULSE
5	C-FIB PULSE WITH NO PACING
6	MULTI-PHASIC C-FIB PULSE AND 5 TIME CONSTANTS DECREMENT OF PACER AMPLITUDE
7	MULTI-PHASIC C-FIB PULSE AND STEADY STATE PACER AMPLITUDE
8	NOT USED
9	NOT USED
10	NOT USED
11	NOT USED
12	NOT USED
13	NOT USED
14	NOT USED
15	BSM MODE

FIG-7

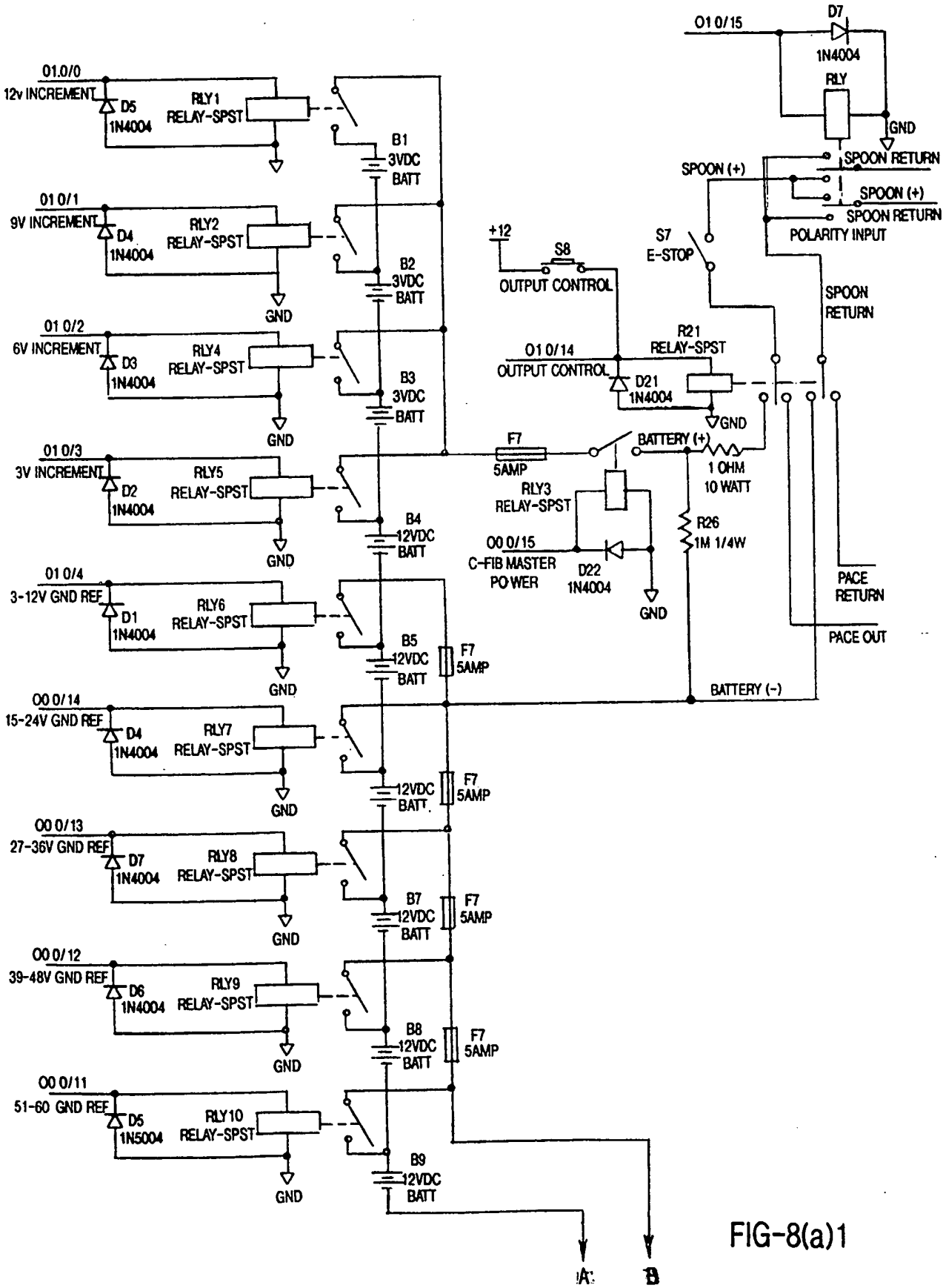

01.0/0
12v INCREMENT
D5
1N4004
RLY1
RELAY-SPST
B1
3VDC
BATT
01 0/1
9V INCREMENT
D4
1N4004
RLY2
RELAY-SPST
B2
3VDC
BATT
GND
01 0/2
6V INCREMENT
D3
1N4004
RLY4
RELAY-SPST
B3
3VDC
BATT
GND
01 0/3
3V INCREMENT
D2
1N4004
RLY5
RELAY-SPST
B4
12VDC
BATT
GND
01 0/4
3-12V GND REF
D1
1N4004
RLY6
RELAY-SPST
B5
12VDC
BATT
F7
5AMP
GND
00 0/14
15-24V GND REF
D4
1N4004
RLY7
RELAY-SPST
12VDC
BATT
F7
5AMP
GND
00 0/13
27-36V GND REF
D7
1N4004
RLY8
RELAY-SPST
B7
12VDC
BATT
F7
5AMP
GND
00 0/12
39-48V GND REF
D6
1N4004
RLY9
RELAY-SPST
B8
12VDC
BATT
F7
5AMP
GND
00 0/11
51-60 GND REF
D5
1N5004
RLY10
RELAY-SPST
B9
12VDC
BATT
GND
01 0/15
D7
1N4004
RLY
GND
SPOON (+)
SPOON RETURN
SPOON (+)
SPOON RETURN
POLARITY INPUT
+12
S8
OUTPUT CONTROL
S7
E-STOP
SPOON
RETURN
01 0/14
OUTPUT CONTROL
R21
RELAY-SPST
D21
1N4004
GND
F7
5AMP
BATTERY (+)
1 OHM
10 WATT
RLY3
RELAY-SPST
R26
1M 1/4W
00 0/15
C-FIB MASTER
POWER
D22
1N4004
GND
PACE
RETURN
PACE OUT
BATTERY (-)
A
B

FIG-8(a)1

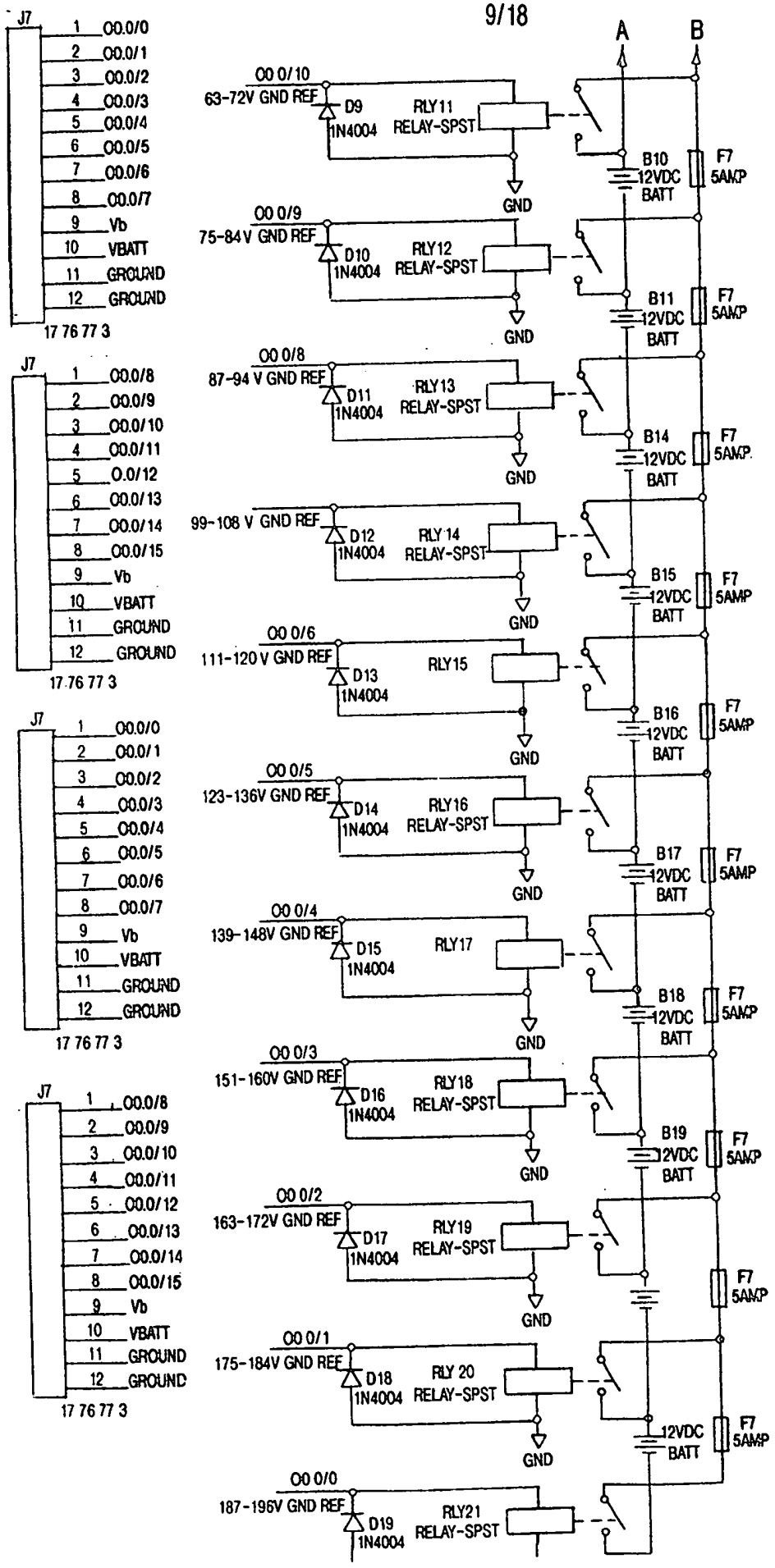

J7
1 O0.0/0
2 O0.0/1
3 O0.0/2
4 O0.0/3
5 O0.0/4
6 O0.0/5
7 O0.0/6
8 O0.0/7
9 Vb
10 VBATT
11 GROUND
12 GROUND
17 76 77 3
J7
1 O0.0/8
2 O0.0/9
3 O0.0/10
4 O0.0/11
5 O.0/12
6 O0.0/13
7 O0.0/14
8 O0.0/15
9 Vb
10 VBATT
11 GROUND
12 GROUND
17 76 77 3
J7
1 O0.0/0
2 O0.0/1
3 O0.0/2
4 O0.0/3
5 O0.0/4
6 O0.0/5
7 O0.0/6
8 O0.0/7
9 Vb
10 VBATT
11 GROUND
12 GROUND
17 76 77 3
J7
1 O0.0/8
2 O0.0/9
3 O0.0/10
4 O0.0/11
5 O0.0/12
6 O0.0/13
7 O0.0/14
8 O0.0/15
9 Vb
10 VBATT
11 GROUND
12 GROUND
17 76 77 3
A
B
O0 0/10
63-72V GND REF
D9
1N4004
RLY11
RELAY-SPST
GND
B10
12VDC
BATT
F7
5AMP
O0 0/9
75-84V GND REF
D10
1N4004
RLY12
RELAY-SPST
GND
B11
12VDC
BATT
F7
5AMP
O0 0/8
87-94 V GND REF
D11
1N4004
RLY13
RELAY-SPST
GND
B14
12VDC
BATT
F7
5AMP
99-108 V GND REF
D12
1N4004
RLY 14
RELAY-SPST
GND
B15
12VDC
BATT
F7
5AMP
O0 0/6
111-120 V GND REF
D13
1N4004
RLY15
GND
B16
12VDC
BATT
F7
5AMP
O0 0/5
123-136V GND REF
D14
1N4004
RLY16
RELAY-SPST
GND
B17
12VDC
BATT
F7
5AMP
O0 0/4
139-148V GND REF
D15
1N4004
RLY17
GND
B18
12VDC
BATT
F7
5AMP
O0 0/3
151-160V GND REF
D16
1N4004
RLY18
RELAY-SPST
GND
B19
2VDC
BATT
F7
5AMP
O0 0/2
163-172V GND REF
D17
1N4004
RLY19
RELAY-SPST
GND
F7
5AMP
O0 0/1
175-184V GND REF
D18
1N4004
RLY 20
RELAY-SPST
GND
12VDC
BATT
F7
5AMP
O0 0/0
187-196V GND REF
D19
1N4004
RLY21
RELAY-SPST

FIG-8(a)2

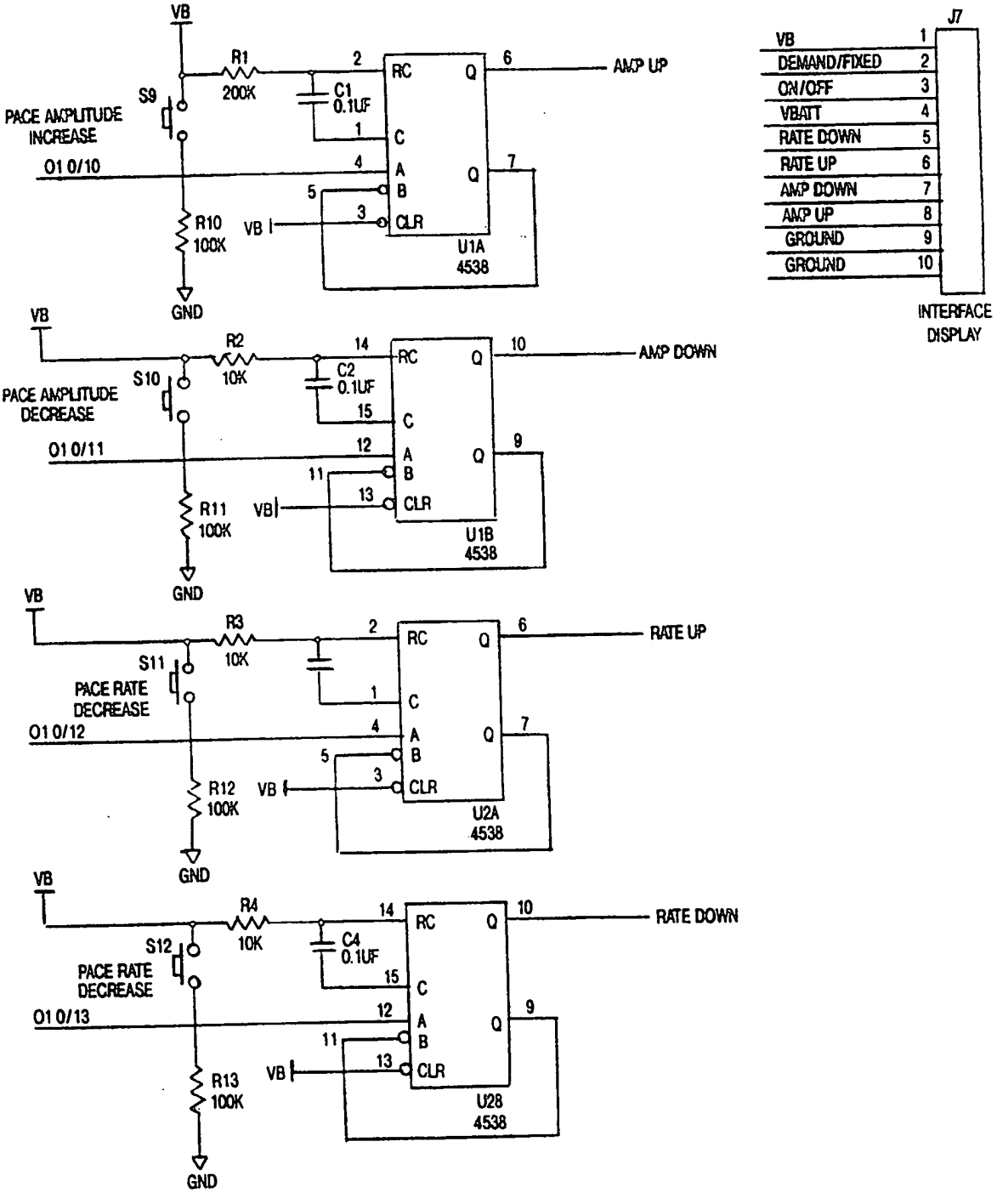

VB
R1
200K
C1
0.1UF
S9
PACE AMPLITUDE INCREASE
O1 0/10
R10
100K
GND
RC
Q
C
A
B
CLR
U1A
4538
AMP UP
R2
10K
C2
0.1UF
S10
PACE AMPLITUDE DECREASE
O1 0/11
R11
100K
U1B
4538
AMP DOWN
R3
10K
S11
PACE RATE DECREASE
O1 0/12
R12
100K
U2A
4538
RATE UP
R4
10K
C4
0.1UF
S12
PACE RATE DECREASE
O1 0/13
R13
100K
U28
4538
RATE DOWN
J7
VB 1
DEMAND/FIXED 2
ON/OFF 3
VBATT 4
RATE DOWN 5
RATE UP 6
AMP DOWN 7
AMP UP 8
GROUND 9
GROUND 10
INTERFACE DISPLAY

FIG-8(b)1

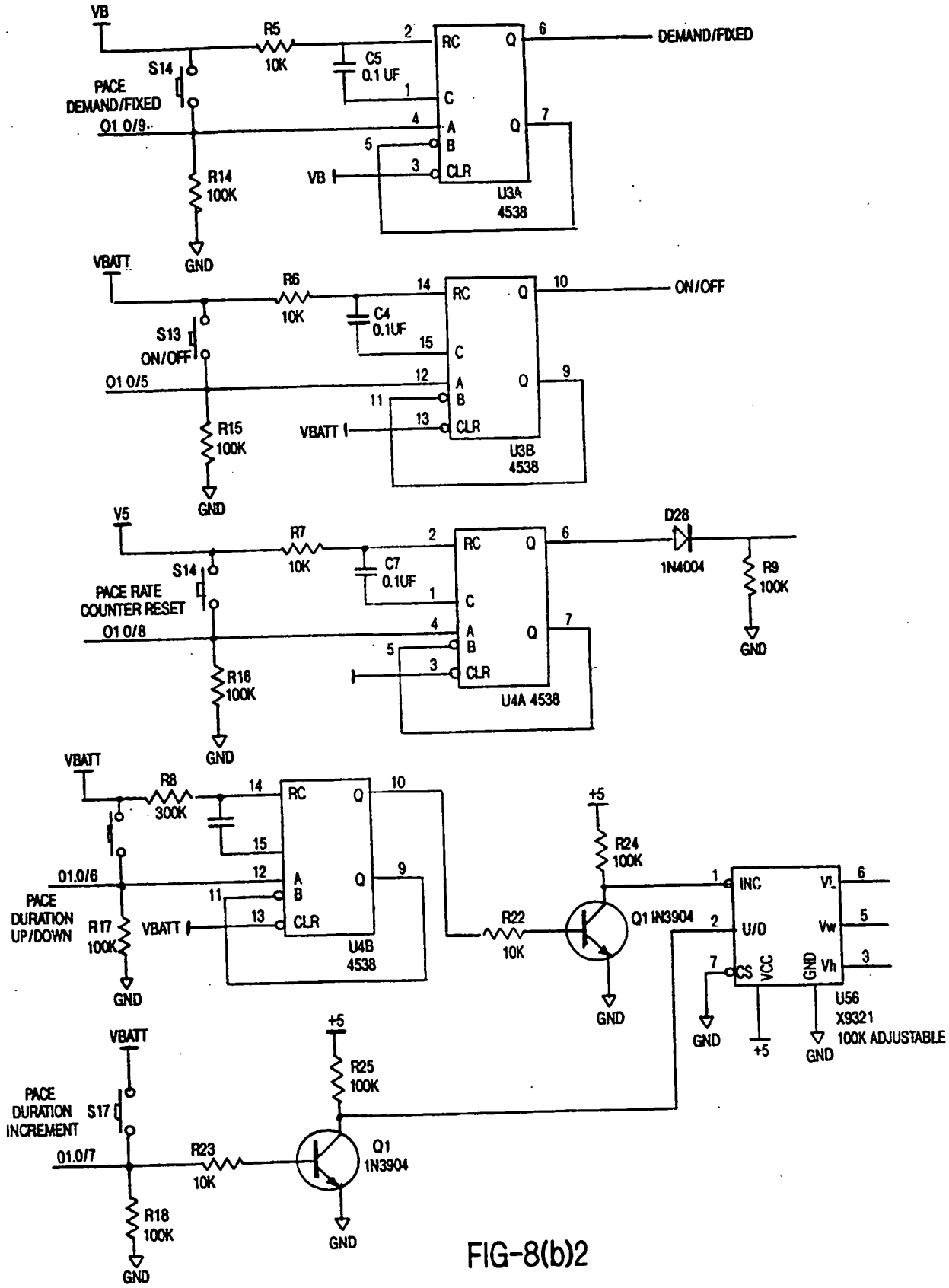
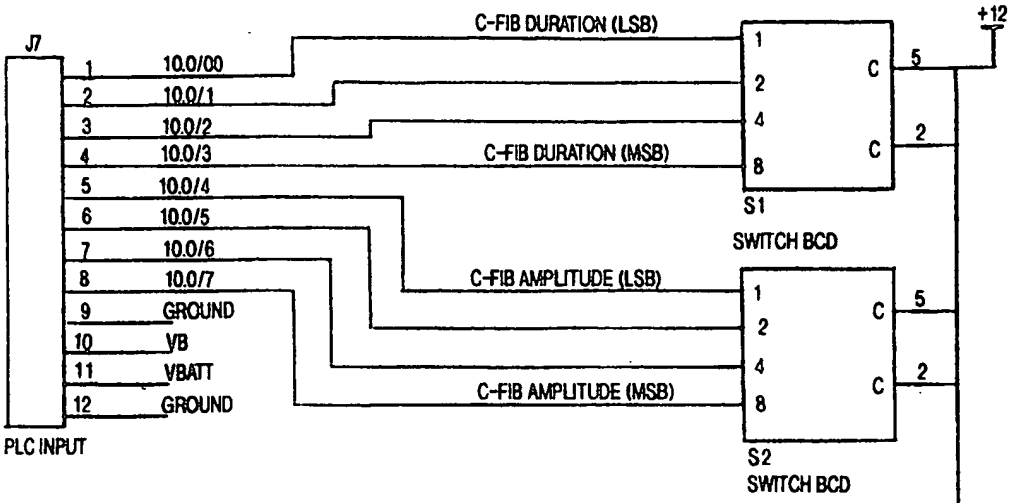
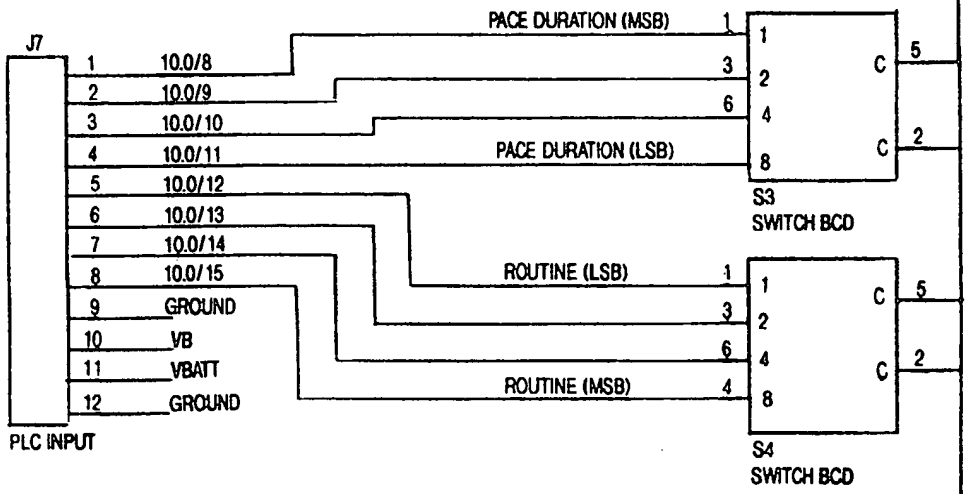
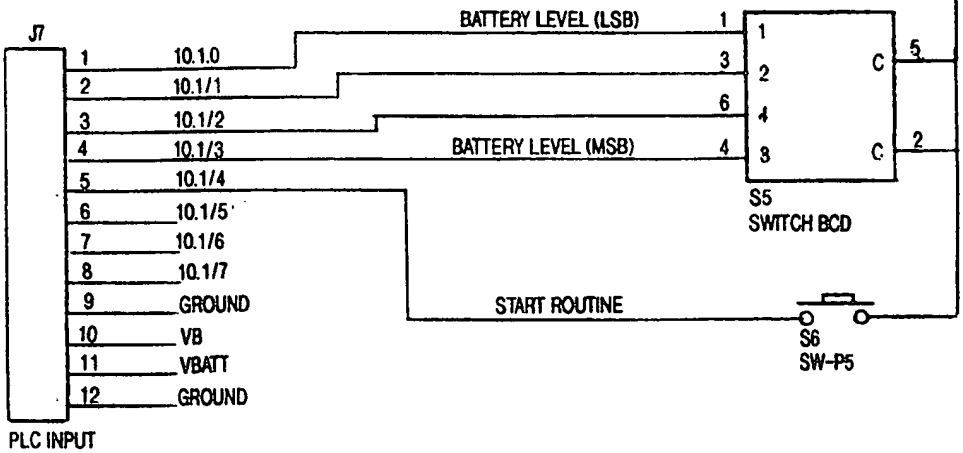
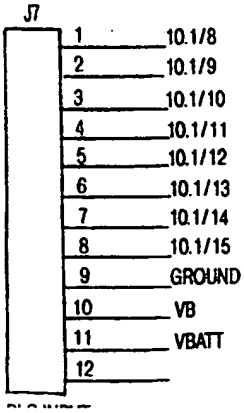

VB
R5
10K
C5
0.1 UF
S14
PACE
DEMAND/FIXED
O1 0/9
R14
100K
GND
RC
Q
C
A
B
CLR
U3A
4538
DEMAND/FIXED
VBATT
R6
10K
C4
0.1UF
S13
ON/OFF
O1 0/5
R15
100K
ON/OFF
V5
R7
10K
C7
0.1UF
S14
PACE RATE
COUNTER RESET
O1 0/8
R16
100K
U4A 4538
D28
1N4004
R9
100K
VBATT
R8
300K
01.0/6
PACE
DURATION
UP/DOWN
R17
100K
U4B
4538
R22
10K
+5
R24
100K
Q1 IN3904
INC
U/D
CS
VCC
GND
Vl
Vw
Vh
U56
X9321
100K ADJUSTABLE
VBATT
PACE
DURATION
INCREMENT
S17
01.0/7
R23
10K
R18
100K
R25
100K
Q1
1N3904

FIG-8(b)2


J7
1 10.0/00
2 10.0/1
3 10.0/2
4 10.0/3
5 10.0/4
6 10.0/5
7 10.0/6
8 10.0/7
9 GROUND
10 VB
11 VBATT
12 GROUND
PLC INPUT
C-FIB DURATION (LSB)
C-FIB DURATION (MSB)
C-FIB AMPLITUDE (LSB)
C-FIB AMPLITUDE (MSB)
S1
SWITCH BCD
S2
SWITCH BCD
+12


J7
1 10.0/8
2 10.0/9
3 10.0/10
4 10.0/11
5 10.0/12
6 10.0/13
7 10.0/14
8 10.0/15
9 GROUND
10 VB
11 VBATT
12 GROUND
PLC INPUT
PACE DURATION (MSB)
PACE DURATION (LSB)
ROUTINE (LSB)
ROUTINE (MSB)
S3
SWITCH BCD
S4
SWITCH BCD


J7
1 10.1.0
2 10.1/1
3 10.1/2
4 10.1/3
5 10.1/4
6 10.1/5
7 10.1/6
8 10.1/7
9 GROUND
10 VB
11 VBATT
12 GROUND
PLC INPUT
BATTERY LEVEL (LSB)
BATTERY LEVEL (MSB)
START ROUTINE
S5
SWITCH BCD
S6
SW-P5


J7
1 10.1/8
2 10.1/9
3 10.1/10
4 10.1/11
5 10.1/12
6 10.1/13
7 10.1/14
8 10.1/15
9 GROUND
10 VB
11 VBATT
12

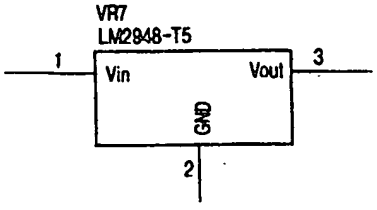

VR7
LM2948-T5
1
Vin
Vout
3
GND
2

FIG-8(c)

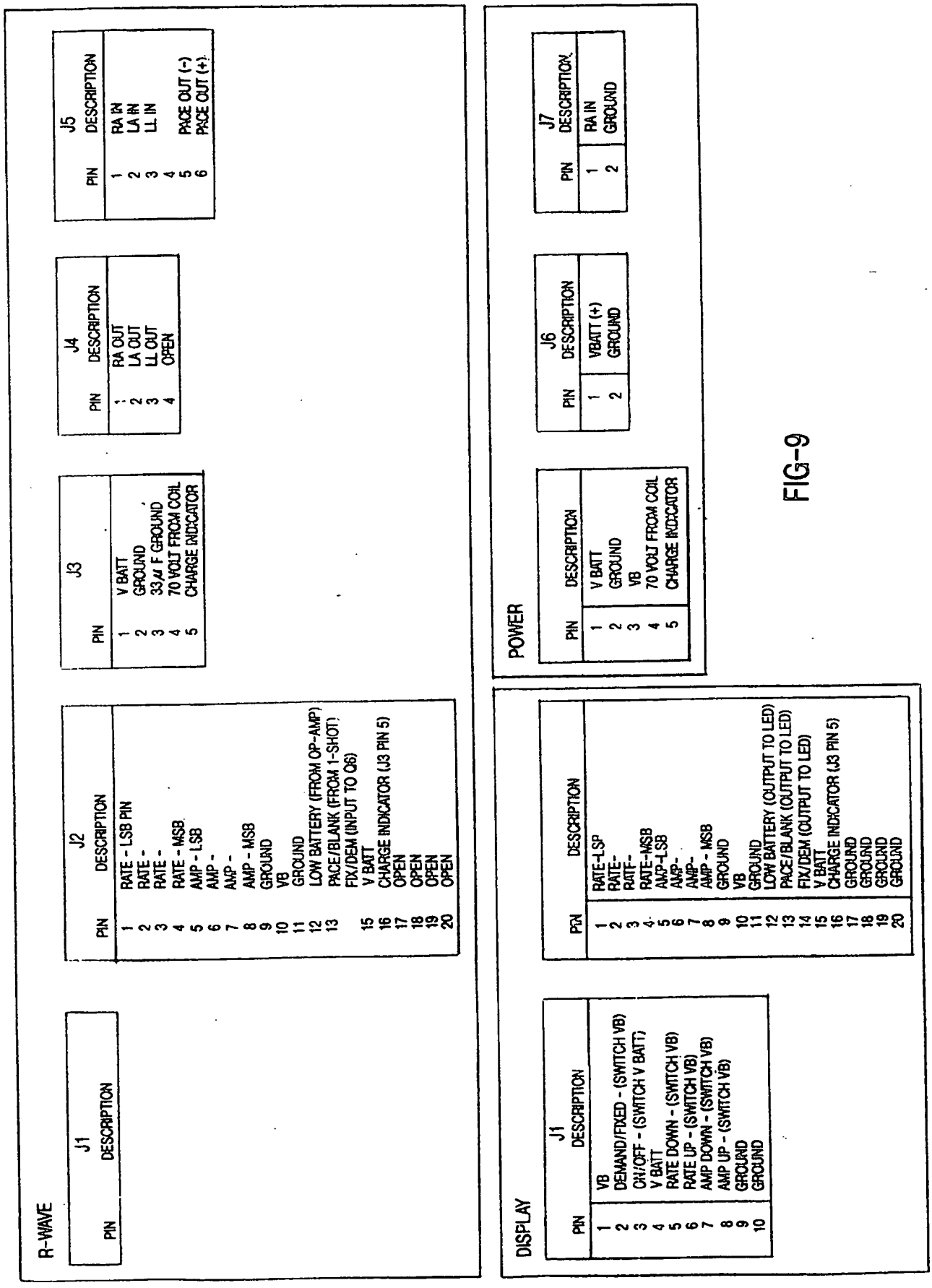

R-WAVE
J1
PIN DESCRIPTION
J2
PIN DESCRIPTION
1 RATE - LSB PIN
2 RATE -
3 RATE -
4 RATE - MSB
5 AMP - LSB
6 AMP -
7 AMP -
8 AMP - MSB
9 GROUND
10 VB
11 GROUND
12 LOW BATTERY (FROM OP-AMP)
13 PACE/BLANK (FROM 1-SHOT)
FIX/DEM (INPUT TO Q6)
15 V BATT
16 CHARGE INDICATOR (J3 PIN 5)
17 OPEN
18 OPEN
19 OPEN
20 OPEN
J3
PIN
1 V BATT
2 GROUND
3 33μ F GROUND
4 70 VOLT FROM COIL
5 CHARGE INDICATOR
J4
PIN DESCRIPTION
1 RA OUT
2 LA OUT
3 LL OUT
4 OPEN
J5
PIN DESCRIPTION
1 RA IN
2 LA IN
3 LL IN
4
5 PACE OUT (-)
6 PACE OUT (+)
POWER
PIN DESCRIPTION
1 V BATT
2 GROUND
3 VB
4 70 VOLT FROM COIL
5 CHARGE INDICATOR
J6
PIN DESCRIPTION
1 VBATT (+)
2 GROUND
J7
PIN DESCRIPTION
1 RA IN
2 GROUND
DISPLAY
J1
PIN DESCRIPTION
1 VB
2 DEMAND/FIXED - (SWITCH VB)
3 ON/OFF - (SWITCH V BATT)
4 V BATT
5 RATE DOWN - (SWITCH VB)
6 RATE UP - (SWITCH VB)
7 AMP DOWN - (SWITCH VB)
8 AMP UP - (SWITCH VB)
9 GROUND
10 GROUND
PIN DESCRIPTION
1 RATE-LSP
2 RATE-
3 RATE-
4 RATE-MSB
5 AMP-LSB
6 AMP-
7 AMP-
8 AMP - MSB
9 GROUND
10 VB
11 GROUND
12 LOW BATTERY (OUTPUT TO LED)
13 PACE/BLANK (OUTPUT TO LED)
14 FIX/DEM (OUTPUT TO LED)
15 V BATT
16 CHARGE INDICATOR (J3 PIN 5)
17 GROUND
18 GROUND
19 GROUND
20 GROUND

FIG-9

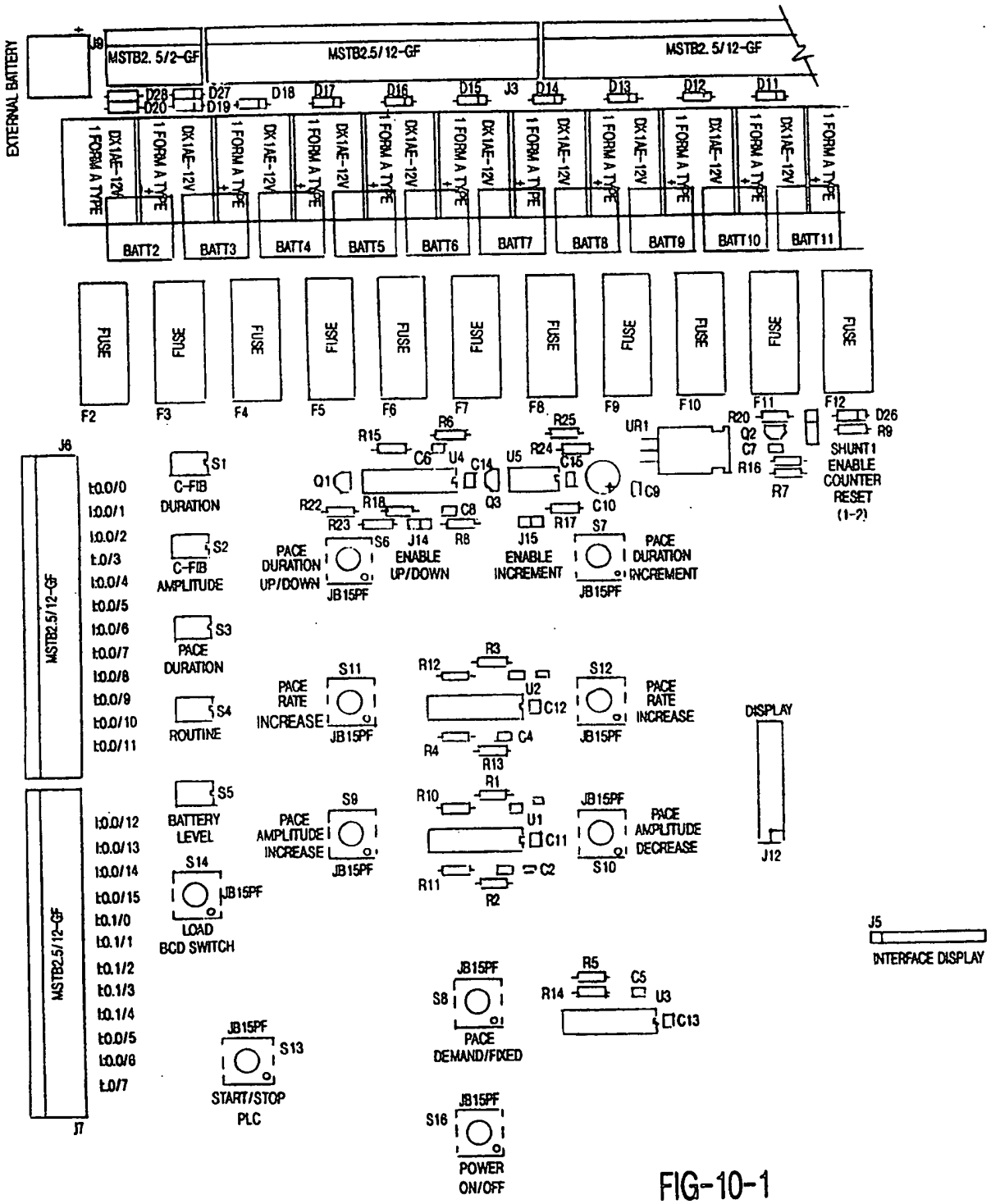

EXTERNAL BATTERY
J9
MSTB2. 5/2-GF
MSTB2.5/12-GF
MSTB2. 5/12-GF
D28
D20
D27
D19
D18
D17
D16
D15
J3
D14
D13
D12
D11
1 FORM A TYPE
DX1AE-12V
BATT2
BATT3
BATT4
BATT5
BATT6
BATT7
BATT8
BATT9
BATT10
BATT11
FUSE
F2
F3
F4
F5
F6
F7
F8
F9
F10
F11
F12
J6
MSTB2.5/12-GF
I:0.0/0
I:0.0/1
I:0.0/2
I:0.0/3
I:0.0/4
I:0.0/5
I:0.0/6
I:0.0/7
I:0.0/8
I:0.0/9
I:0.0/10
I:0.0/11
S1
C-FIB DURATION
S2
C-FIB AMPLITUDE
S3
PACE DURATION
S4
ROUTINE
S5
BATTERY LEVEL
S14
JB15PF
LOAD BCD SWITCH
MSTB2.5/12-GF
I:0.0/12
I:0.0/13
I:0.0/14
I:0.0/15
I:0.1/0
I:0.1/1
I:0.1/2
I:0.1/3
I:0.1/4
I:0.0/5
I:0.0/6
I:0.0/7
J7
R15
R6
C6
U4
C14
Q1
R22
R18
R23
C8
Q3
J14
ENABLE UP/DOWN
R8
S6
PACE DURATION UP/DOWN
JB15PF
R25
R24
U5
C15
C10
C9
R17
J15
ENABLE INCREMENT
S7
PACE DURATION INCREMENT
JB15PF
UR1
R20
Q2
C7
R16
R7
F11
F12
D26
R9
SHUNT1 ENABLE COUNTER RESET (1-2)
S11
PACE RATE INCREASE
JB15PF
R3
R12
U2
C12
C4
R4
R13
S12
PACE RATE INCREASE
JB15PF
DISPLAY
J12
S9
PACE AMPLITUDE INCREASE
JB15PF
R1
R10
U1
C11
C2
R11
R2
JB15PF
S10
PACE AMPLITUDE DECREASE
J5
INTERFACE DISPLAY
JB15PF
S8
PACE DEMAND/FIXED
R5
C5
R14
U3
C13
JB15PF
S13
START/STOP PLC
JB15PF
S16
POWER ON/OFF

FIG-10-1

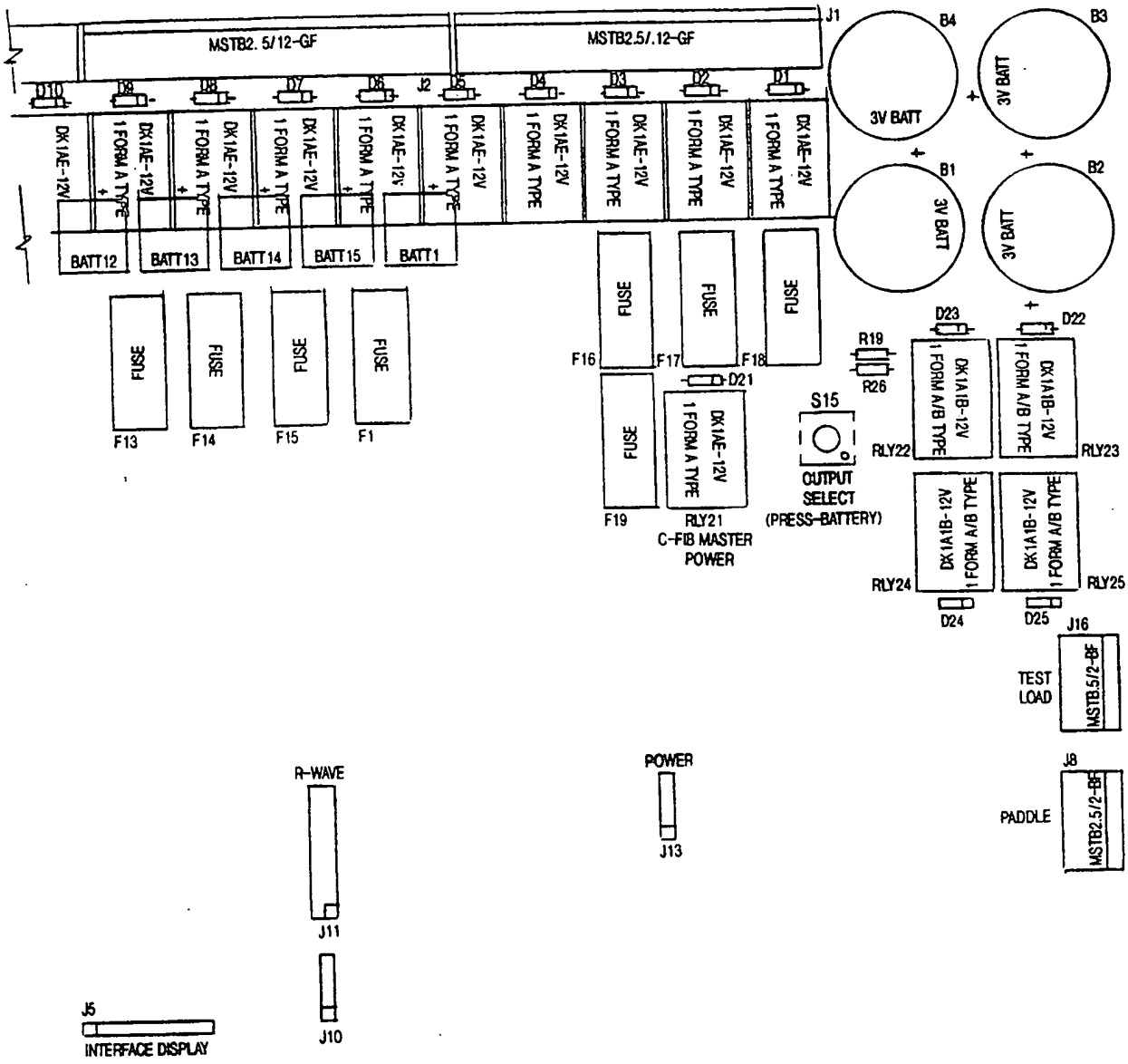

J1
MSTB2. 5/12-GF
MSTB2.5/.12-GF
D10
D9
D8
D7
D6
J2
D5
D4
D3
D2
D1
DK1AE-12V
1 FORM A TYPE
BATT12
BATT13
BATT14
BATT15
BATT1
B4
B3
B1
B2
3V BATT
FUSE
F13
F14
F15
F1
F16
F17
F18
F19
D21
D22
D23
R19
R26
S15
OUTPUT SELECT
(PRESS-BATTERY)
DK1A1B-12V
1 FORM A/B TYPE
RLY22
RLY23
RLY21
C-FIB MASTER POWER
RLY24
RLY25
D24
D25
J16
TEST LOAD
MSTB.5/2-BF
J8
PADDLE
MSTB2.5/2-BF
R-WAVE
J11
POWER
J13
J10
J5
INTERFACE DISPLAY

FIG-10-2

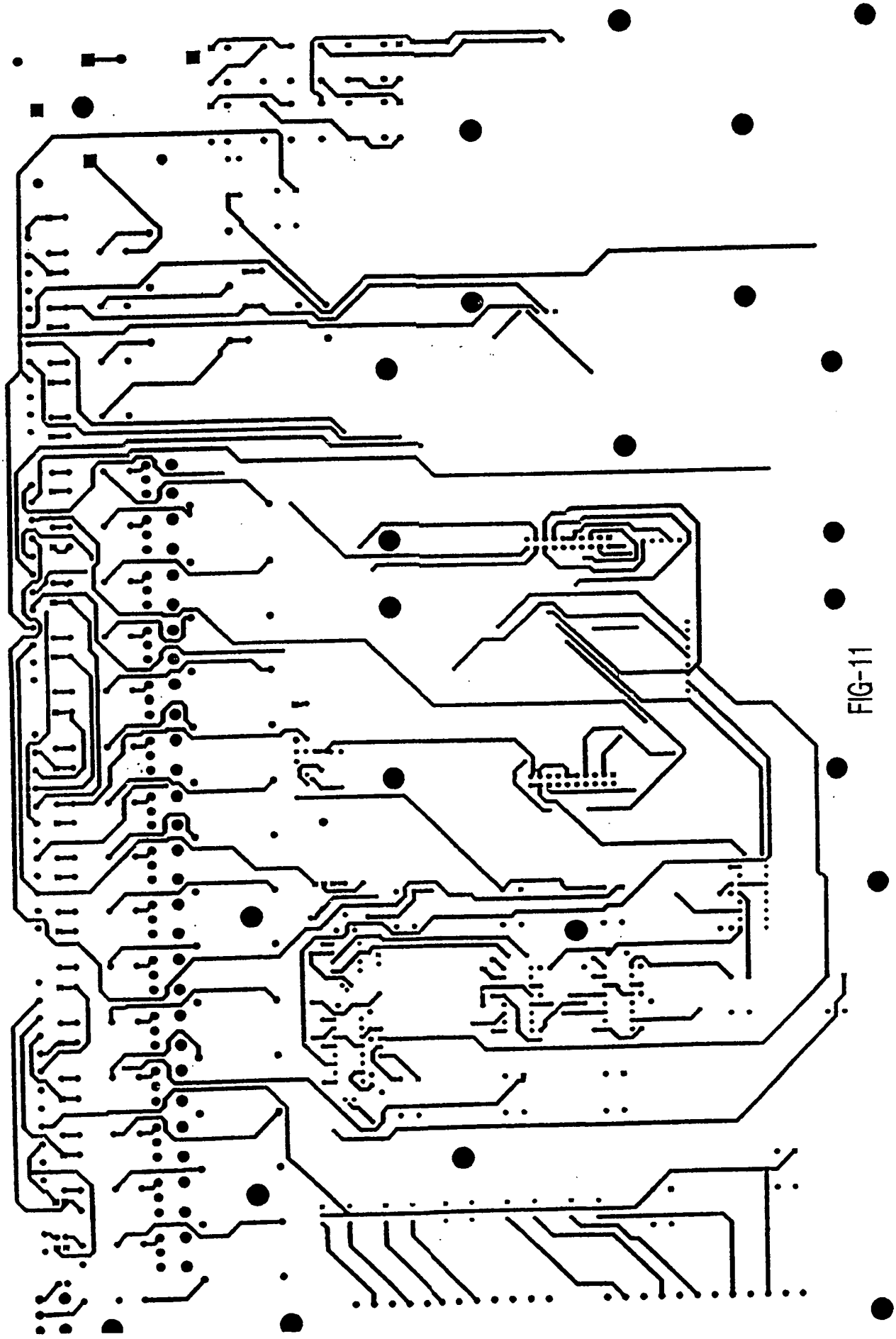


FIG-11

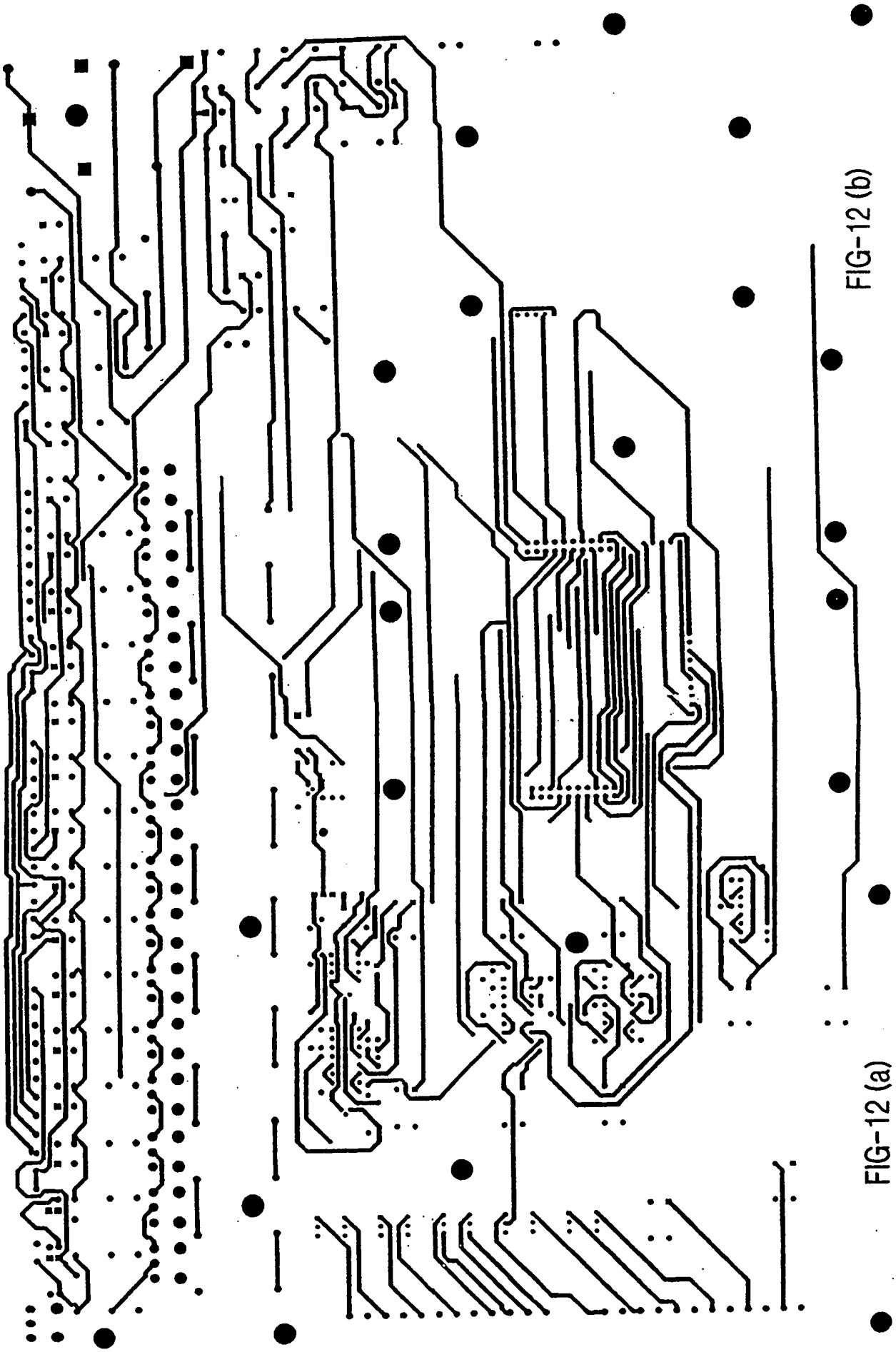


FIG-12 (b)

FIG-12 (a)

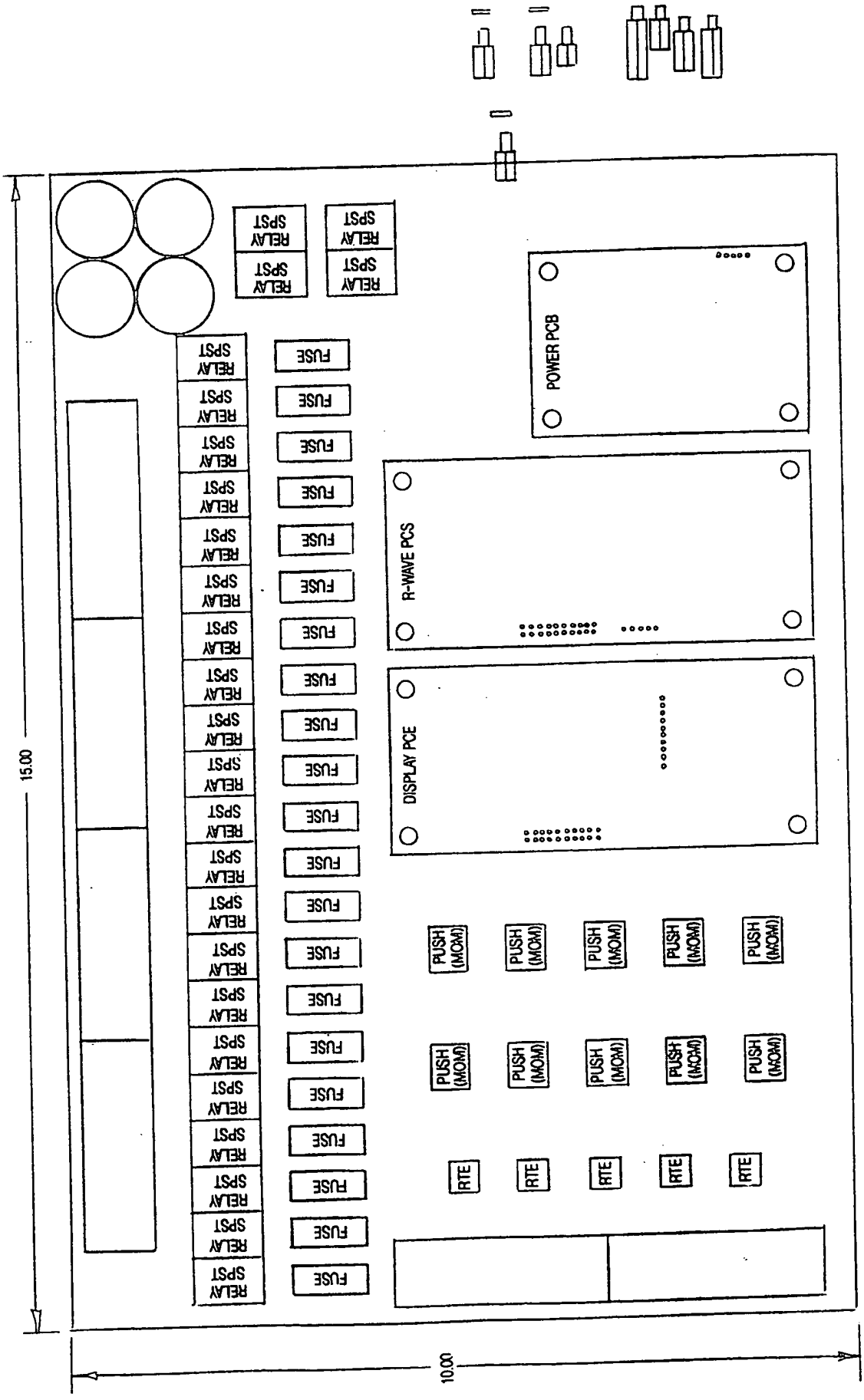


FIG-13 (b)

FIG-13(a)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 98/14751

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61N1/39 A61N1/362

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 391 187 A (FREEMAN GARY A) 21 February 1995	1,4,5
A	see the whole document	2,3

X	CHARBONNIER F M: "EXTERNAL DEFIBRILLATORS AND EMERGENCY EXTERNAL PACEMAKERS" PROCEEDINGS OF THE IEEE, vol. 84, no. 3, 1 March 1996, pages 487-499, XP000590780	1,4,5
A	see the whole document	2,3

X	US 5 078 134 A (HEILMAN MARLIN S ET AL) 7 January 1992	1,4,5
A	see the whole document	2,3

X	US 4 693 253 A (ADAMS THEODORE) 15 September 1987	1-5
	see the whole document	

	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
29 September 1998	08. 10. 98

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Allen, E

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 645 569 A (AYERS GREGORY M) 8 July 1997 see the whole document ---	1,4,5
A	US 5 522 853 A (KROLL MARK W) 4 June 1996 see column 9, line 63 - column 10, line 5 -----	2,3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 98/14751

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 6-10
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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